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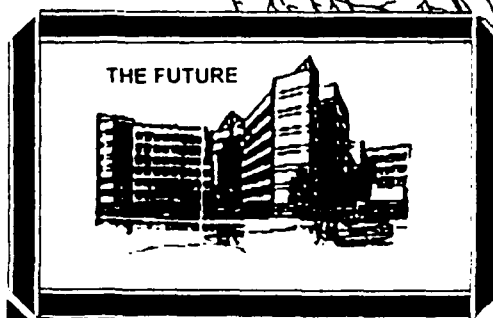
DEPARTMENT OF CLINICAL INVESTIGATION

# ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1993  
VOLUME 1

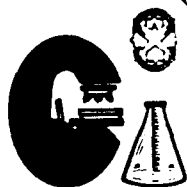
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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234



# REPORT DOCUMENTATION PAGE

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13. ABSTRACT (Maximum 200 words) Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Use Committee for registration with the Department of Clinical Investigation during FY 1993, and known publications and presentations by the Brooke Army Medical Center professional staff. A detail summary sheet of each protocol giving the objective, technical approach, and progress is presented.				
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## FOREWORD

1993 was another productive year for the Brooke Army Medical Center (BAMC) Department of Clinical Investigation (DCI). The continuing productivity of the DCI is due to the support of the members of the DCI and from the Commander, BG Russ Zajtchuk; the Deputy Commander, COL David A. McFarling; the Chief of Staff, COL Douglas A. Barton; and the training program chairmen.

The philosophy of the DCI is to support and encourage the academic pursuits of the housestaff and professional staff. The performance of quality research is only one aspect of this goal. Other aspects are to develop intellectual curiosity and the abilities to design clinical studies, analyze data, interpret results, explain the research efforts in written and oral form, and critically analyze scientific literature. The goal of the DCI is to assist in developing and fostering these research skills in academicians, scientists, and clinicians in the belief that clinical research promotes continuing medical education and ultimately benefits the patient. In keeping with this goal, Drs. Jean Johnson, John Ward, Earl Grant, and James Lamiell have continued to present their package of clinical research instruction to several clinical services.

Opening of the new BAMC animal research facility took place in September 1993. This was primarily the result of efforts by our previous veterinarian, CPT Terri Clark and our present veterinarian, MAJ Carol L. Eisenhauer. The new animal research facility will double our capability for supporting animal use protocols. This represents a substantial improvement since the number of animal use protocols continues to increase.

There has been a continuing increase in the acquisition of extramural funding to support the research endeavors of BAMC. The DCI serves as a resource and support service for investigators in obtaining these funds. Some DCI goals for 1994 include increasing efforts to obtain extramural funding and broaden the research teaching program to include a discussion of ethics in science and medicine.

This has been a fruitful year for the DCI. MAJ Grant and myself are indebted to the staff of the DCI and BAMC who have supported us during the past year. We are also grateful to those who preceded us and whose efforts made much of the progress of the past year possible. We look forward to another year of service to BAMC.

JAMES M. LAMIELL  
Colonel, MC  
Chief, Department of Clinical  
Investigation

COMMANDER'S AWARD WINNERS

First Place

Intubating Conditions with Mivacurium  
Chloride: A Comparison of Neuromuscular  
Blockade Monitoring at the Adductor Pollicis  
and the Orbicularis Occuli

Samuel C. Sayson  
Captain, MC  
Anesthesiology & Operative Service  
Department of Surgery

Second Place

Pharmacodynamic Doppler Determination of  
Mitral Valve Area in Patients with  
Significant Aortic Regurgitation

David M. Mego  
Major, MC  
Cardiology Service  
Department of Medicine

Third Place

Capillary Refill Time in the Normal Newborn

Barton B. Cook  
Captain, MC  
Department of Pediatrics

\* \* \* \* \*

NOTE: The Commander's Award Recipients for Training Year 1993 were listed in  
the FY 92 Annual Report due to administrative error.

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## UNIT SUMMARY

### - FISCAL YEAR 1993

#### A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

#### B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-3, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

#### C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Lamiell, James M.	COL	61F	Chief
Grant, Earl, Jr.	MAJ	68C	Biochemist
Yeager, Curtis	MAJ	68A	Microbiologist
Eisenhauer, Carol L.*	MAJ	64B	Veterinary Lab Animal Officer
Clark, Terri**	CPT	64B	Veterinary Lab Animal Officer
Duncan, Rory D.**	SSG	92B3R	NCOIC
Irizarry, Zulma	SGT	92B20	Med Lab Specialist
Guzman, Edwin*	SSG	92B30	Med Lab Specialist
White, James*	SPC	92B30	Med Lab Specialist

Hunter, Scott*	SPC	92B30	Med Lab Specialist
Ruiz, Javier	SGT	91T20	Animal Care Specialist
Yoquelet, Curtis	SGT	91T20	Animal Care Specialist
Brand, Gary**	SPC	91T10	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Ward, John A.	GS13	00401	Research Physiologist
Johnson, Jean M.	GS12	00610	Research Nurse
Reeb, Barbara	GS11	00644	Medical Technologist
Davey, Inid	GS11	00644	Medical Technologist
(salaried by CHAMPUS- assigned to DCI)			
Trevino, Sylvia*	GS11	00644	Medical Technologist
(salaried by CHAMPUS- assigned to DCI)			
Chapa, Isidoro	GS7	00645	Medical Technician
Williams, Dannie	GS7	00404	Biological Lab Technician
Rios, Roberto***	GS9	01020	Med Scientific Illustrator
Smith, Helen J.*	GS9	00301	Clin Research Protocol Coord
Aguero, Lynda D.*	GS6	01087	Editorial Assistant
Johnson, Maurine E.*	GS5	19110	Secretary

\* Assigned Jul 93, Sep 93, Mar 93, Jan 93, Feb 93

\*\* Reassigned Aug 93, Oct 93, Aug 93

\*\*\* Assigned to IMD with duty in DCI

Personnel:	Authorized	Required	Assigned
Officers -	4	9	4
Civilians -	13	16	13
Enlisted -	9	10	6

#### D. Funding

Type	Fiscal Year 92	Fiscal Year 93
Civilian personnel		
to include benefits	575,734.00	569,368.16
Consumable supplies	156,888.00	163,354.05
Civilian contracts		
to include consultants	14,689.00	14,600.00
TDY	13,817.00	4,883.00
Noninvestment equipment		
(Minor MEDCASE)	655.00	-----
Other OMA	-----	-----
OMA Total	761,784.00	718,384.00
MEDCASE	133,139.00	130,517.57
CEEP	55,575.00	126,488.77
Other (Bone Marrow Unit)	227,180.00	10,915.00

<u>Military</u>	<u>661,545.00</u>	<u>605,550.00</u>
<u>TOTAL</u>	<u>1,839,223.00</u>	<u>2,344,060.55</u>

Grants:

- a. U.S. Army Medical Research and Development Command - \$14,760.00
- b. Southwest Oncology Group - \$124,500.00
- c. Other Nonfederal Gifts - \$43,360.01

Protocol Disposition FY 93

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 94</u>
FY 77	-		0	1
FY 85	1		0	1
FY 86	0		1	1
FY 87	1		2	3
FY 88	1	0	0	6
FY 89	6	0	2	12
FY 90	7		7	38
FY 91	10		13	64
FY 92	23			72
FY 93	<u>11</u>		<u>31</u>	<u>146</u>
	63		56	344

Training Protocols

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 94</u>
FY 86	0		0	4
FY 87	0		0	2
FY 89	1		0	0
FY 90	0		0	1
FY 92				4
FY 93	<u>1</u>		<u>0</u>	<u>4</u>
	2		0	15

Oncology Group Protocols

SWOG	0		32	158
POG	0		23	62
GOG	<u>0</u>		<u>1</u>	<u>48</u>
	0		39	255

Number of resident and fellowship programs: 23  
Number of residents and fellows with approved protocols: 92  
Number of approved protocols held by this group: 75

Other training programs that use Clinical Investigation: University of Texas Health Science Center at San Antonio; University of Texas, Austin; Academy of Health Sciences Physical Therapy Branch.  
Number of approved protocols held by this group: 18

Number of hospital staff members with approved protocols: 173  
Number of approved protocols held by this group: 230

Drug evaluation/comparison studies: 94 (Does not include Oncology Group Protocols)

#### Significant Changes in the Last Year/Changes for the Future

We have become more proactive in recruiting investigators in the MEDCEN.

We are expanding our collaborative efforts with extramural sources. MRDC, the University of Texas Health Science Center at San Antonio and Austin, Cancer Therapy Research Center, and the State Chest Hospital are all collaborators.

#### Changes in Support of Growing Graduate Medical Education Requirements

There is a continuing requirement to have documented classroom hours devoted to research topics such as ethics, statistics, informed consent, protocol development, etc. These requirements are being met by going to the departments and offering tailored instruction for each units needs.

We continue to benefit from gifts and grants offered through the Jackson Foundation and organizations such as Facilitators of Applied Clinical Trials (FACT), the National Kidney Foundation and other not for profit organizations. Approvals for gifts of support are being processed in a more expeditious manner due to a better understanding of the approval process.

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#### Publications and Presentations Reported in 1993

Publications: 146  
Abstracts: 180  
Presentations: 192

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**DEPARTMENT OF THE ARMY  
Brooke Army Medical Center  
Fort Sam Houston, TX 78234-6226  
DEPARTMENT OF CLINICAL INVESTIGATION**

**PRESENTATIONS**

**DEPARTMENT OF CLINICAL INVESTIGATION**

Lamiell, JM: Some Design Considerations for Using Neural Networks to Classify Western Blot Densitometer Scans. 96th Annual Meeting of the Texas Academy of Science, Denton, TX, Mar 93.

Lamiell, JM: Detection of Type-Specific Herpesvirus Antibodies by Neural Network Classification of Western Blot Densitometer Scans. 1993 IEEE International Conference on Neural Networks, San Francisco, CA, Mar 93.

Lamiell, JM: The Effect of Dobutamine Infusion on Fluid Volume Requirements Following Hemorrhage. 16th Annual Conference on Shock, Sante Fe, NM, Jun 93.

Johnson, JM: Needs of Research Personnel at the Clinial Research Site. Presented to FACT Clinial Research Site Facilitators, 26 Jan 93, San Antonio, TX.

Johnson, JM: Nursing Research Basic Skills Workshop (VA-BAMC Project), Mar 93, Audie L. Murphy VA Hospital, San Antonio, TX.

**DEPARTMENT OF EMERGENCY MEDICINE**

Williams, M. Risk Management in the Emergency Department. Joint Services Symosium in Emergency Medicine, San Antonio, TX, 29 Apr 93.

Knapp, MJ: Altered Mental Status. University of Texas Health Science Center at San Antonio, Medical Student Lecture, 28 Jul 93.

Rodgers, KG: Approach to the Emergency Medicine Patient. University of Texas Health Science Center at San Antonio, Medical Student Lecture, 14 Jul 93.

Smith, BA: Magnesium in TCA Overdose. International Society for Academic Emergency Medicine, Cambridge, England, 15 Sep 93.

Stack, LB: Comparison of Sublingual Succinylcholine vs. Other Routes in Sheep Model. International Society for Academic Emergency Medicine, Cambridge, England, 15 Sep 93.

**DEPARTMENT OF MEDICINE**

**Allergy-Immunology Service:**

Ortiz, AA. Common Variable Hypogammaglobulinemia with Elevated Liver Enzymes. Fitzsimons Allergy-Immunology Meeting, Denver, CO.

**Presentations (continued)**

**Dyer, PD.** ACE Inhibitors. Fitzsimons Allergy-Immunology Meeting, Denver, CO.

**Cardiology Service:**

**Hays, JV, Gilman, JK and Rubal, BJ.** The Effect of Magnesium on Ventricular Rate Control in Atrial Fibrillation. AHA presentation.

**Arendt, MA.** Head-Upright Tilt Susceptibility in Healthy Young Adults with Prior Syncope. ACP presentation.

**Dramiga, SA.** Comparison of Re-hospitalization and Risk Factor Modification in Patients Participating in Phase III and Home Rehabilitation Programs. ACP presentation.

**Mega, DM.** Factors Influencing the Doppler Pressure Half-Time in Mitral Stenosis. ACP presentation.

**Nottestad, SY.** Tetralogy of Fallot in a 71 Year Old Patient with New Onset Hypoxemia. ACP presentation.

**Wright, WT.** High-Fidelity Hemodynamic Library from the Cardiac Catheterization Laboratory at BAMC: A Unique Hemodynamic Waveform Database for Cardiology. ACP presentation.

**Rubal, BJ.; Bailey, SR.** Altered Regional Vascular Taper During Changes in Blood Pressure. Presented at Experimental Biology, 28 Mar - 1 Apr 93, New Orleans, LA.

**Bulgrin, JR.; Rubal, B; Thompson, R; Moody, JM.** Comparison of Short-Time Fourier, Wavelet and Time-Domain Analyses of Intracardiac Sounds. Rocky Mountain Bioengineering Symposium, Inc., 2-3 Apr 93, San Antonio, TX.

**Bulgrin, JR; Thompson, R; Rubal, BJ; Moody, JM.** Time-Frequency Distributions of Heart Sound Energy. Texas Academy of Science 1993 Annual Meeting.

**Rubal, BJ.** Central Aortic Blood Pressure Variability During Cardiac Catheterization. Texas Academy of Science 1993 Annual Meeting.

**Dermatology Service:**

**Coots NV.** Physical Diagnosis of the Skin. 18D Special Operations Crs, FSHT 8 Jun 93.

**Coots NV:** All you ever wanted to Know about Contraceptives. Sam Houston High School, 17 Apr 93.

**Coots NV:** Diseases of the Skin. Presented to SOMED Sergeants Crs (twice: 3 Aug 93 and 7 Sep 93).

**Presentations (continued)**

**Coots NV:** Physical Examination of the Skin. Presented to SOMED Sergeants Crs 13 Sep 93.

**Elston DM:** Bugs and Stings. Presented at University of Texas Health Sci Cen, San Antonio, TX, Aug 93.

**Gastroenterology Service:**

**Francis J.** Effect of Omeprazole on Barrett's Epithelium - Initial Report at Three Months of Therapy. Army ACP Meeting Nov 92.

**Cassaday, M.** Prospective Evaluation of Foley Catheter as Replacement Gastrostomy Tube: Experience in 27 Patients.

**Parker A.** Dicida Hepatogram - A Numeric Measure of Liver Function. Army ACP Meeting Nov 92.

**Carrougner, J.** Upper Endoscopic Ultrasound (EUS) The Brooke Experience. Army ACP Meeting Nov 92.

**Angueira, C.** Effects of Large Volume Paracentesis on Pulmonary Function Tests in Patients with Tense Cirrhotic Ascites. Army ACP Meeting Nov 92.

**Shaffer, R.** Gastric Acid Secretion in HIV-1 Positive Patients. Army ACP Meeting Nov 92.

**Kepeczyk, T.** A Prospective Evaluation of Iron Deficiency Anemia with Upper and Lower Endoscopy. Army ACP Meeting Nov 92.

**McGovern, TW.** Hepatitis C Transmission in Sexual But Not in Casual Contacts of Index Cases. Army ACP Meeting Nov 92.

**Kadakia, S.** Esophageal Dilatation with Polyvinyl Bougies Using a Guidewire with Markings Without the Aid of Fluoroscopy - An Update. Army ACP Meeting Nov 92.

**Kadakia, S.** Pneumatic Dilation Using Rigiflex Achalasia Dilators in Patients with Primary Esophageal Achalasia. Army ACP Meeting Nov 92.

**Parker, A.** Periampullary Polyps in Gardner's Syndrome - Successful Treatment with Sulindac. Army ACP Meeting Nov 92.

**Kadakia, S.** Comparison of Foley Catheter as a Replacement Gastrostomy Tube with Commercial Gastrostomy Tube. Army ACP Meeting Nov 92.

**Angueira, C.** Effects of Large Volume Paracentesis on Pulmonary Function Tests in Patients with Tense Cirrhotic Ascites. Digestive Disease Week, Boston, MA, May 93.



**Presentations (continued)**

Carrougner, J. The Prevalence of Colonic Neoplasms in Patients with Breast Carcinoma. Digestive Disease Wk, Boston, MA, May 93.

Kadakia, S. Anticoagulation and Endoscopy: Preliminary Results of a Survey of ASGE Members. Digestive Disease Week, Boston, MA, May 93.

Francis, J. Effect of Ameprazole on Barrett's Epithelium - Initial Report at Three Months of Therapy. Digestive Disease Week, Boston, MA, May 93.

Kadakia, S. Comparison of Foley Catheter as a Replacement Gastrostomy Tube with Commercial Gastrostomy Tube. Digestive Disease Week, Boston, MA, May 93.

Kadakia, S. Prospective Evaluation of Patients with Positive Fecal Occult Blood Test at Digital Rectal Exam. Digestive Disease Week, Boston, MA, Nov 92.

Kepczyk, T. A Prospective Evaluation of Iron Deficiency Anemia with Upper and Lower Endoscopy. Digestive Disease Week, Boston, MA, May 93.

Parker, A. Nuclear Hepatogram--A Numeric Measure of Liver Function. Digestive Disease Week, Boston, MA, May 93.

**General Medicine Service:**

Farrington, C. Pravastatin vs Simvastatin, A Comparative Trial. American College of Physician, San Francisco, CA, Oct 92.

Marple, R. Medical Student Attitudes toward Internal Medicine. Army ACP, San Francisco, CA, 5 Nov 92.

Wroblewski, C; Kadakia SC, Kadakia AS. Prevalence of Proximal Colonic Neoplasms in Asymptomatic Patients over 50 with Negative Fecal Occult Blood for Flex Sigmoidoscopy. AGA, May 93.

Marple, R. Common Symptoms in Ambulatory Medicine: Patient Consensus and Expectations. National Society of General Internal Medicine, 28 Apr 93, Crystal City, VA.

**Hematology/Oncology Service:**

Anderson LL; Thomas DE; Berger TG; Vukelja SJ: Cutaneous Pigmentation Following Daunorubicin Chemotherapy. J. Am Acad Dermatol 26:255-256, 1992.

Vukelja SJ; Baker, WJ; Jeffreys P; Reeb BA; Pick T: Nonbacterial Thrombotic Endocarditis Clinically Mimicking Veno-Occlusive Disease of the Liver Complicating Autologous Bone Marrow Transplantation. Am J. Clin Onc 15(6):500-502, 1992.

Bowen KJ; Vukelja SJ: The Hypercoagulable Patient. Postgraduate Medicine 91:117-132, 1992.

**Presentations (continued)**

Wiebe VJ, Koester S; Lindberg M; Emshoff V; Baker WJ; DeGregorio MW: Toremifene and its Metabolites Enhance Doxorubicin Uptake in Estrogen Receptor Negative Multidrug Resistant Human Breast Cancer Cells. Invest New Drugs 10:63-71, 1992.

Wall JG; Burris HAB III; Von Hoff DD; Rodriguez G; Kneuper-Hall R; Shaffer D; O'Rourke TJ; Brown T; Weiss G; Clark G; McVea S; Brown J; Johnson R; Friedman C; Smith B; Mann WS; and Kuhn J: A Phase I Clinical and Pharmacokinetic Study of Topoisomerase I Inhibitor Topotecan (SK&F 104864) given as an Intravenous Bolus every 21 Days. Anti-Cancer Drugs 3:337-345, 1992.

Burris HA III; Hanauske AR; Johnson RK; Marsha MH; Kuhn JG; Hilsenbeck SG; Von Hoff D: Activity of Topotecan, a New Topoisomerase I Inhibitor, Against Human Tumor Colony-Forming Units in Vitro. J Natl Cancer Institute, 84:1816-1820, Dec 92.

Zaloznik AJ; Giudice RA: Gastric Hodgkin's Disease: Recurrence After Autologous Bone Marrow Transplant. Military Med, 157:617-619, Nov 92.

Brown TD; Burris HA, Eckardt JR; O'Rourke TJ, Rodriguez GI; Wall JG and Weiss GR: New Anticancer Agents in Cancer Chemotherapy and Biological Response Modifiers Annual 13, HM Pinedo, DL Longo and BA Cabner, ed. Chapter 10, pg 115-155, 1992.

**Infectious Disease Service:**

Morris, J; Kelly, JW. Absorption of Ketoconazole by HIV Patients. Infec Dis Annual Mtg - ICAAC, New Orleans, LA, 15-20 Oct 93.

Schrank, JH; McAllister, CK; Kelly, JW; Kazragis, R. Comparison of Cefepime and Ceftazidime in Gram Neg Bacteremia.

Schrank, JW. Use of PCR for Diagnosis of Histoplasmosis. ICAAC.

Dooley, D. Resistance in Complylobacter Fetus Bacteremia. ICAAC.

Longfield, R; Odegaard, V; Jordon, P; Karwacki, J. Efficacy of OSHA Blood-borne Pathogen Training in Enhancing Hepatitis B Immunization Rates and Reducing Parenteral and Mucosal Exposures to Blood in Health Care Workers. 33rd Interscience Conference on Antimicrobial Agents and Chemotherapy.

Reddy, RK; Dooley, DP. Abdominal Coccidiomycosis.

Schrank, J; Konkol, K; Tryon, V. Development and Application of Polymerase Chain Reaction for the Detection of Histoplasma Capsulatum. 33rd Interscience Conference on Antimicrobial Agents and Chemotherapy.

Kazragis, R; Dever, LL; Barbour, AG. Activity of Vancomycin and Ceftriaxone Against Borrelia SPP in Mice: Implication for Treatment on Antimicrobial Agents and Chemotherapy.

**Presentations (continued)**

**Nephrology Service:**

Wortham, Wm G. Donation & Transplantation in the Military. South Texas Organ Bank, Inc.

Wortham, Wm G. Clinical Essentials of Metabolic Acidosis. Annual Convention & Scientific Assembly of the National Medicine Assn, San Antonio 7-12 Aug 93.

Barr, JG. Renal Workshops (Renal Failure, Volume and Electrolyte Disturbances). Univ of Texas Health Science Center at San Antonio, Sep 93.

**Neurology Service:**

Halliday, A. Neurology Grand Rounds - CPC Discussant. University of Texas Health Science Center, San Antonio, TX, 7 Apr 93.

**Pulmonary Disease Service:**

Johnson, JE; Loube DI; Nauscheutz, KK; Hayes, JA. The Effect of Forcep Size on the Adequacy of Specimens Obtained by Transbronchial Biopsy. National Mtg of the American College of Chest Physicians.

Johnson, JE; Hayes, JA. The Effect of Breathing Oxygen on Forced Expiratory Flow and Maximum Voluntary Ventilation (MVV) in Patients with COPD. Army Regional Mtg of the American College of Physicians.

Peacock, MD; Johnson, JE; Blanton, HM. Complications of Fiberoptic Bronchoscopy in Patients with Severe Airway Obstruction and in Patients with Normal Pulmonary Function. Army Regional Mtg of the American College of Physicians.

Hayes, JA; Kumke, K; Johnson, JE. The Effect of Supplemental Oxygen on Pulmonary Compliance in Patients with Emphysema. Army Regional Mtg of the American College of Physicians.

Brassard, JM; Strollo, PJ; Markowicz S. Evaluation of the Effects of Supplemental Oxygen and Air-flow Parameters on Oxygen Delivery with BIPAP Ventilation. Army Regional Mtg of the American College of Physicians.

Morgan, JA; Lawrence, RA; Peacock, MD; Jenkinson, SG. Selenium Requirements for BCNU-Induced Protection from Hyperbaric Hyperoxia. Army Regional Mtg of the American College of Physicians.

Brassard, JM; Johnson, JE. Paradoxical Response of Dead Space Ventilation to Exercise in Unilateral Absence of a Pulmonary Artery. Army Regional Mtg of the American College of Physicians.

Anders, GT; Blanton, HM; Timmons, J; Hartshorne, MF; Johnson, JE. Gallium-67 SPECT Scanning in Human Immunodeficiency Virus (HI) Patients. Army Regional Mtg of the American College of Physicians.

**Presentations (continued)**

Loube, DI; Johnson, JE; Nauscheutz, KK; Hayes, JA. Effect of Forcep on the Adequacy of Specimens Obtained by Transbronchial Biopsy. Army Regional Mtg of the American College of Physicians.

**Rheumatology Service:**

Older, SA. Systemic Lupus Erythematosus Following Vaccination. Presented at the American College of Physicians Army Regional Meeting, 7 Nov 92, San Francisco, CA.

**DEPARTMENT OF NURSING**

Yoder, L. Myths of Mentoring. Alamo Area Nurse Executives, San Antonio, TX, Feb 93.

Sexton, P., and Richard, L. Competency Based Assessment and Orientation. St. Luke's Lutheran Nurse Manager and Administrative Council Meeting, San Antonio, TX, Feb 93.

Yoder, L. Oncologic Emergencies. Senior Nursing Students at the University of Texas Health Science Center, San Antonio, TX, Oct 92.

Yoder, L. Career Development Relationships for Nurses, Vanderbilt University, Nashville, TN, Nov 92.

Yoder, L. More Than Mentoring. Association of Military Surgeons of United States, Nashville, TN, Nov 92.

Yoder, L. Paths to Success Study Findings. Recruiting Command Regional Conference, Nashville, TN, Nov 92.

Ford, L. Critical Care Course. University of Texas Health Science Center, San Antonio, TX, 2-9 Mar 93.

Mountcastle, G. Panel Member on Roles and Responsibilities of Pediatric Clinical Nurse Specialists. Graduate Nursing Students, University of Texas Health Science Center, San Antonio, TX, Dec 92.

Darm, R. Hypothermia--The Physiologic Effect and An Evaluation of Core Temperature Corrected Liquid Crystal Display as an Indicator of Temperature in the Post Anesthesia Care Unit. Junior Professional Development Day, Fort Sam Houston, Apr 93.

Hodge, N. Case Management. Principles of Advanced Nursing Administration, Fort Sam Houston, Apr, Aug 93.

Yoder, L. Relationships Experienced by Army Staff Nurses and Outcomes of Professionalism, Job Satisfaction and Intent to Stay. Leadership Conference for Nurses, Wayne State University and Detroit Medical Center, Jun 93;

**Presentations (continued)**

**Clinical Head Nurse and Principles of Advanced Nursing Administration Courses, Apr/May 93.**

**Yoder, L. Career Development Relationships. Nurse Managers and Wardmasters, USAF Wilford Hall, San Antonio, Apr 93.**

**Yoder, L. Biologic Response Modifiers and Overview of Bone Transplant Radiotherapy. Oncology Review Course, American Cancer Society, Aug 93.**

**Yoder, L. Overview of Care of the Transplant Patient. Regional Dietician/Nutritional Care Course, BAMC, Jun 93.**

**Yoder, L.; Mountcastle, G; Noble, L. Presentations in Chemo-therapy/Bone Marrow Transplant Courses sponsored by Wilford Hall, AMVMC and BAMC, Apr, May 93.**

**DEPARTMENT OF OBSTETRICS AND GYNECOLOGY**

**Gehlbach, D. Immunohistochemical Evaluation of Estrogen Receptors in Uterine Leiomyoma. ACOG Armed Forces District Meeting, Norfolk, VA, Nov 92.**

**Mayer, AR. Oncogene Expression in Ovarian Primary and Metastatic Malignant Sites. 1992 Armed Forces District Mtg of American College OB/GYN, Norfolk, VA, Nov 92.**

**Mayer, AR. Ovarian Cancer Staging: Does It Require a Gynecologic Oncologist? 1991 Armed Forces District Meeting of American College of OB/GYN, Norfolk, VA, Nov 92.**

**Gehlbach, D. Grand Rounds: Osteoporosis. William Beaumont AMC, Sep 93.**

**DEPARTMENT OF PATHOLOGY**

**Smith, JI. Pathology of Hemorrhagic Fever with Renal Syndrome. 20th Annual Seminar in Forensic Medicine, Colby College.**

**Lloyd, WC. Embryonal Rhabdomyosarcoma of the Orbit. University of Texas Health Science Center at San Antonio Ophthalmology Grand Rounds.**

**DEPARTMENT OF PEDIATRICS**

**Tiway, CM. Use of Hormone Containing Cosmetic Preparation in Children: Possible Association with Premature Sexual Development. Presented at the Pediatric Endocrine Society of Texas, Oklahoma, Louisiana and Arkansas Meeting, Fort Worth, TX, 22-24 Mar 93.**

**Connor, J. Peptic Ulcer Disease in Children. Pediatrics for the Practitioner, San Antonio 10-13 Jun 93.**

**Presentations (continued)**

Inscore, S. Update in Pediatric Asthma. Pediatrics for the Practitioner, San Antonio, 10-13 Jun 93.

Anderson, R. Anticonvulsants: When to Start and When to Stop. Pediatrics for the Practitioner, San Antonio, 10-13 Jun 93.

Hays, M. Case Studies in Cardiology. Pediatrics for the Practitioner, San Antonio, 10-13 Jun 93.

Glasow, P. Case Studies in Cardiology. Pediatrics for the Practitioner, San Antonio, 10-13 Jun 93.

Heiman, H. Controversies in Management of Neonatal Hyperbili-rubinemia. Pediatrics for the Practitioner, San Antonio, 10-13 Jun 93.

Roscelli, J. Hematuria and Proteinuria. Pediatrics for the Practitioner, San Antonio 10-13 Jun 93.

**DEPARTMENT OF RADIOLOGY**

Heironimus, J., at University of Texas Health Science Center at San Antonio:

Renal Function Studies, 2 Oct 92

Left Ventricular Imaging, 20 Jan 93

Renal Scintigraphy, 26 Jan 93

SPECT Technology, 8 Jan 93

Non PET Brain Studies, 26 Feb 93

Case Presentations, 8 Apr 93

Renal Scintigraphy, 3 May 93

Heironimus, J., at Radiology Wilford Hall Medical Center:

Left Ventricular Imaging, 10 Jan 93

Renal Scintigraphy, 6 Jan 93

Cases, 6 Jan 93

Heironimus, J. Renal Scintigraphy. Nuclear Medicine Technologists at the San Antonio Society of Nuclear Medicine Meeting, 20 Feb 93.

Katz, N., at University of Texas Health Science Center at San Antonio:  
Adrenal Imaging, 7 Jan 93

**Presentations (continued)**

Gastrointestinal Bleeding, 8 Jan 93

Parathyroid Scintigraphy, 29 Jan 93

Gastrointestinal Bleeding, 10 Feb 93

Katz, N., at Radiology Wilford Hall Medical Center:

Adrenal Imaging, 11 Jan 93

Gastrointestinal Bleeding, 11 Jan 93

Thomas, J. (Radiopharmacist):

Nuclear Pharmacy. U.S. AMEDD Center & School,  
17 Nov 92 and 14 Dec 92

Nuclear Pharmacy. University of Texas, Austin, TX  
18 Nov 92

Radiopharmacy Quality Control. Wilford Hall Medical Center, 25  
Jan 93.

Thomas, J. Nuclear Pharmacy. American Society of Hospital Pharmacists,  
Austin, TX 6 Mar 93.

**DEPARTMENT OF SURGERY**

**General Surgery:**

Jaffin, J. Trammatismos Graves Decolon. XXV Curso Annual deUrgencis Medico  
Quirurgicas Cordoba, Argentina, 16 Sep 93.

Jaffin, J. Complicaciones en Traumatismos Del Abdomen. Same as above.

**Otolaryngology Service:**

Ramirez, S. Paranasal Sinus Cancer. University of Texas at San Antonio, TX,  
5 Jan 93.

Hayes, D. Midfacial Fractures. University of Texas at San Antonio, TX, 19  
Jan 93.

Burton, D. Adenotonsillar Disease. University of Texas at San Antonio, TX,  
16 Mar 93.

Hayes, D. Radiology of Paranasal Sinus. University of Texas, San Antonio,  
TX, 8 Dec 92.

Rumans, T. Fungal Sinusitis. University of Texas, San Antonio, TX, 4 May 93.

**Presentations (continued)**

**Malis, D.** Tissue Expansion of Facial Nerve in Animal Model. Texas Association of Otolaryngology Meeting, Houston TX 14 May 93.

**Davey, P.** Suture Selection & Cartilage Healing. University of Texas, San Antonio, TX, 1 Jun 93.

**Burton, DM.** Airway Manifestations of Esophageal Reflux. Pediatric Otolaryngology & Allergy Update, San Diego, CA, 11 Jun 93.

**Burton, DM.** Benign Pediatric Neck Masses. Pediatric Otolaryngology and Allergy Update, San Diego, CA, 12 Jun 93.

**Burton, DM.** Airway Manifestations of Esophageal Reflux. Pediatric Otolaryngology Update, Galveston, TX, 25 Jun 93.

**Hayes, D.** Frontal Sinusitis. UTSA Grand Rounds, San Antonio, TX 10 Aug 93.

**Urology Service:** Thompson, Ian M.:

The Case for Immediate Inguinal Lymphadenectomy for Carcinoma of the Penis. Annual Meeting of The American College of Surgeons. New Orleans, Louisiana, 14 Oct 92.

Chemoprevention of Prostate Cancer with Finasteride. Plenary Session of Southwest Oncology Group Annual Mtg. St Louis, Missouri, 18 Oct 92.

Controversies in the Management of Clinical Stage C Carcinoma of the Prostate. Symposium on Prostate and Bladder Cancer, sponsored by the Uniformed Services University of the Health Sciences. Orlando, FL, 31 Oct 92.

Treatment Options for Stage A2 and B Carcinoma of the Prostate. Symposium on Prostate and Bladder Cancer, sponsored by the Uniformed Services University of the Health Sciences. Orlando, Florida, 31 Oct 92.

Potential Problems with Early Detection of Prostate Cancer. Annual Meeting of South Central Section, American Urological Association. Galveston, Texas, 1 Nov 92.

Confounds and Biases with Early Detection of Prostate Cancer. American Urological Association Allied - Alamo Chapter Symposium on Urologic Diseases. San Antonio, Texas, 7 Nov 92.

Management of Localized Prostate Cancer. Southern Medical Assn. San Antonio, Texas, 13 Nov 92.

Potential Problems with Early detection of Prostate Cancer. Department of Medicine, Grand Rounds, Indiana Univ School of Medicine, Indianapolis, Indiana, 9 Dec 92.



**Presentations (continued)**

**Chemoprevention of Prostate Cancer. Salt Lake Surgical Society, 9 Feb 93.**

**Screening for Prostate Cancer. Surgical Grand Rounds, University of Utah Medical Center, 10 Feb 93.**

**Chemoprevention of Prostate Cancer. Third Annual Quality of Life Symposium, St. Mary's Medical Center, Long Beach, CA, 20 Feb 93.**

**The Natural History of Prostate Cancer. Oncology Symposium, University of Miami, Orlando, FL, 26 Feb 93.**

**Management of Stage C Carcinoma of the Prostate. American Urological Assn Postgraduate Course, Houston, TX, 5 Mar 93.**

**Chemoprevention of Prostate Cancer - New Opportunities. Texas Medical Assn, Dallas, TX, 20 Mar 93.**

**Management of Stage 1 Nonseminomatous Germ Cell Tumors. Hospital Central Militar, Mexico City, 50th Anniversary Symposium in Urology. Mexico City, 26 Mar 93.**

**Options for the Management of Stage I Nonseminomatous Germ Cell Tumors. 50th Anniv Military Medical Center Seminar. Mexico City, MX 26 Mar 93.**

**Treatment of Locally-Confining Prostate Cancer. 50th Anniversary Military Medical Center Seminar. Mexico City, 27 Mar 93.**

**Early Detection of Prostate Cancer. University of Nebraska Seminar. Wichita, NE, 3 Apr 93.**

**Management of Locally-Advanced Prostate Cancer. University of Nebraska Seminar, Wichita, NE, 4 Apr 93.**

**Treatment of Benign Prostatic Hyuperplasia. United States Air Force Clinic, Randolph Air Force Base, San Antonio, TX, 12 Apr 93.**

**Chairman, Urology Practice Management Seminar, San Antonio, TX, 14-15 May 93.**

**Panel Discussion - Early Diagnosis of Prostate Cancer. Society of Urologic Oncology Annual Meeting, San Antonio, TX, 1 May 93.**

**Chairman, Postgraduate Course on the Management of Complications of Prostate Cancer. Annual Meeting Amer Urological Assn, San Antonio, TX, 16 May 93.**

**Additive Value of Prostatic Acid Phosphatase in the Staging of Carcinoma of the Prostate. Annual Meeting Amer Urological Assn, San Antonio, TX, 17 May 93.**

#### **Presentations (continued)**

**Management of Locally-Confined Prostate Cancer.** Annual Meeting of the American Urological Assn, Allied, San Antonio TX 19 May 93.

**Chairman, First Annual Postgraduate Course on Radical Prostec-tomy,** Sponsored by FACT and Brooke Army Medical Center, San Antonio, TX, 21 May 93.

**Confounds Associated with the Early Detection of Prostate Cancer.** Postgraduate Seminar in Medical Oncology, Indiana Univ Medical Center. The Homestead, VA, 6 Aug 93.

**Potential Biases Associated with the Early Detection of Prostate Cancer.** National Medical Association Annual Mtg, San Antonio, TX, 9 Aug 93.

**Opportunities for Chemoprevention of Prostate Cancer.** University of Texas - San Antonio Postgraduate Course, San Antonio, TX, 11 Sep 93.

**Chemoprevention of Prostate Cancer.** South Texas Medical-Surgical Seminar. Isla De Pesca, Costa Rica, 19 Sep 93.

**Early Detection of Prostate Cancer.** South Texas Medical-Surgical Seminar. El Ocotal, Costa Rica, 24 Sep 93.

#### **NUTRITIONAL CARE DIVISION**

**Tefft, R.** Validation of a Food Frequency Questionnaire in Southern Black Females. AMSC 1993 Mary Lipscomb Hamrick Research Course, Silver Springs, MD, 2-6 Aug 93.

**Thomas, V.** Effects of Chromium Supplementation on Plasma Lipids and Glucose Tolerance of Individuals With and Without Non-Insulin Dependent Diabetes Mellitus. AMSC 1993 Lipsomb Hamrick Research Course, Silver Springs, MD, 2-6 Aug 93.

#### **PHYSICAL MEDICINE AND REHABILITATION SERVICE**

**Bryan, JM.** Nonclinical Competencies for Physical Therapist's Consulting with Business and Industry. American Physical Therapy Association Combined Section's Meeting, San Antonio, TX 5 Feb 93.

**Bryan, JM.** Nonclinical Competencies: A Survey of Industrial Physical Therapists. American Physical Therapy Association Combined Section's Meeting, San Antonio, TX, 5 Feb 93.

**Rice, H.** Proprioceptive Rehabilitation of Ankle Injuries. American Physical Therapy Association Combined Section's Meeting San Antonio, TX, 4 Feb 93.

**Liening, D.** A Comparison of Polydioxone & Silicone Plastic in Prevention of Adhesive Otitis Media. Amer Academy of Otolaryn-gology, Minneapolis, MN 30 Sep 93.

**Presentations (continued)**

Rice, H. Isokinetic Testing and Exercise. Physical Therapist Assistant Training Program, St. Phillip's College, San Antonio, TX, 5 Feb 93.

Bryan, JM. Continuing Education: Maximizing the Transfer of Learning to Patient Care. Central District Texas Physical Therapy Association, San Antonio, TX, 22 Apr 93.

Rice, H. A Test of Eccentric Isotonic Contraction on One Repetition Maximum Exercise. Texas Physical Therapy Association Annual Conference, Austin, TX, 30 Apr 93; and Mary L. Hamrich Rsch Crs, Silver Spring, MD, 2-6 Aug 93.

Bryan, JM. Nonclinical Competencies: A Survey of Industrial Physical Therapists. Texas Physical Therapy Association Annual Conference, Austin, TX, 30 Apr 93.

Scott, R. Legal & Ethical Issues in Physical Therapy. Arkansas Physical Therapy Association, West Memphis, AK, 11 Sep 93.

Bergeron, A. Body Mechanics/Prevention of Musculoskeletal Overuse Syndromes. Fort Sam Dental Activities mtg 19 Aug 93.

**PREVENTIVE MEDICINE SERVICE**

Karwacki, J; Oliverson F. PVNT MED Environmental Concerns. University of Texas Health Science Center MPH Program, San Antonio, TX 9 Apr 93.

Karwacki, J. Role of Post Prev Med Officer. AMEDD&CS 6A-F5 Prev Med Course.

Karwacki, J. US Arm Health Promotion. USAF Health Promotion Conf, Brooks AFB, San Antonio, TX 28 Sep 93.

Gray, PJ. Cholesterol Intervention Program. US Army Health Promotion Conf, Palm Desert, CA, 13-18 Jun 93.

## **PUBLICATIONS**

### **DEPARTMENT OF CLINICAL INVESTIGATION**

Lamiell, JM: Computer Auditing of Surgical Operative Reports Written in English. Thesis (M.S.), Univ of TX at San Antonio, Fall 92.

Lamiell, JM; Ward, JA; Hilliard JK: Detection of Type-Specific Herpesvirus Antibodies by Neural Network Classification of Western Blot Densitometer Scans. Proc 1993 IEEE International Conference on Neural Networks, 1731, 1993.

Mozingo, D; Rochon, R; Lamiell, JM: The Effect of Dobutamine Infusion on Fluid Volume Requirements Following Hemorrhage Circulatory Shock, Supplement 2:11, 93.

Lamiell, JM; Ward, JA; Hilliard, JK: Some Design Considerations for Using Neural Networks to Classify Western Blot Densitometer Scans. Proc Texas Academy of Science 96th Annual Meeting, 101, 93.

Johnson, JM; Reineck, C; Daigle-Bjerke, A; Goupil, N; Captain C: Understanding Research Articles: A Pilot Study of Critical Reading of Research Publications. Journal of Nursing Staff Development. Accepted for publication Sep 93.

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### **DEPARTMENT OF EMERGENCY MEDICINE**

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### **Pulmonary Disease:**

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Nelson, B; Mayer, A. Prognostic Impact of Retroperitoneal Nodal Involvement in Stage IIIC Ovarian Carcinoma.

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Piper, J. Association of Maternal but not Fetal Glucose Metabolism with Fetal Growth Retardation. Society for Gynecologic Investigation, Mar-Apr 93, Toronto Canada.

Higby, K. The Prostaglandin Inhibitor Sulindac is Significantly Transported Across the Human Placenta. Society of Perinatal Obstetricians, Mar 93, San Francisco, CA.

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### **DEPARTMENT OF PATHOLOGY**

Peacock, M; Morris, M; Johnson, J; Lloyd W. Acquired Immunoproliferative Lesion (AIL) Presenting as Spontaneous Pneumothorax. (Abstract)

### **DEPARTMENT OF SURGERY**

#### **General Surgery Service:**

Schulz; Powell; Burris; Nguyen; Jaffin; Malcolm. Effects of Diaspirin Crosslinked Hemoglobin on Blood Pressure Blood Loss and Survival in a Model of Uncontrolled Hemorrhage.

# Detail Summary Sheet

Date: 31 Dec 93      Protocol Number C-18-88      Status: Ongoing

Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein

Start date: 16 Dec 88

Estimated completion date:

Principal Investigator:  
Gerald A. Merrill

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Clinical Investigation

Associate Investigator(s):  
Paul M. Horowitz, PhD, UTHSC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA  
cost: \$4,690.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitomes and demonstrate conformational changes involving the rhodanese epitomes by monitoring changes in binding affinities.

Technical Approach: The study plan is to develop a series of antibodies to use in an attempt to better understand the structure-function relationships of a model protein, rhodanese (thiosulfate;cyanide sulfurtransferase). Knowledge of the relationships of between protein structure and protein functions will provide insight into the manipulation of proteins that have medical relevance, including hormones and enzymes. Such knowledge might then permit synthesis via genetic engineering of designer rescue proteins that could be used therapeutically.



**Progress:** Study of the effect of the amino terminus of rhodanese in refolding of the enzyme have been completed. The amino terminus of rhodanese is essential for the effective refolding of the protein into an active enzyme. This was determined by evaluation of the regain of activity following urea denaturation for both intact enzyme and enzyme in which the amino terminal 45 residues was removed by limited tryptic digestion of native enzyme. These results were submitted and accepted for publication in the Journal of Biological Chemistry (268:15611-20; 1993).

Further mapping of the epitope recognized by one of the monoclonal antibodies to rhodanese was accomplished using the enzyme devoid of the amino terminal 45 amino acids using limited tryptic digestion of the native enzyme. The resulting 31 kDa protein was electrophoresed using denaturing SDS polyacrylamide gel electrophoresis. The proteins of the gel were electronically transferred to a support membrane (Immobilon) and tested with each monoclonal and polyclonal antibody presently available. One monoclonal antibody (designated as MAB11) had been previously mapped to the amino terminal cyanogen bromide fragment of the enzyme (residues 1-73). This antibody did not bind to a synthetic peptide corresponding to residues 1-17 of the enzyme indicating the epitope recognized by MAB11 was not entirely within the 1-17 sequence. The blotting experiments with trypsin cleaved enzyme indicated that the epitope was not expressed on the 31 kDa daughter species, suggesting that the epitope is found in the sequence between residues 17 and 45. Another monoclonal antibody (designated as R207) which had also been shown to recognize an epitope on the amino terminal portion of rhodanese which does not overlap the MAB11 epitope and which also did not recognize the 1-17 synthetic peptide was able to recognize both the parent and the 31 kDa tryptic fragment in the blotting experiments. Thus the epitope recognized by R207 was also further mapped to the 45-73 amino acid segment of rhodanese. The mapped regions support previous data showing that the MAB11 epitope can be expressed without significant loss of structure and activity whereas the R207 epitope can not.

MAB11 was evaluated for its ability to influence refolding and to protect rhodanese against denaturation. Initial experiments indicated that MAB11 totally inhibited refolding when present in the refolding media to which denatured enzyme was added. When MAB11 ascites fluid was added to native enzyme, there was an acceleration of the rate at which rhodanese activity was lost (over 4-8 hours). However, the activity slowly regained over the next 48 hours to achieve activities approximately equal to the initial activity of the enzyme. To better characterize this response, MAB11 was purified from the ascites fluid by protein G affinity chromatography and the effect of the purified antibody on protection and refolding determined. The purified antibody when added to native enzyme did not demonstrate the biphasic response previously observed. There was a protective effect against denaturation in dilute solution, but the antibody was no more effective than a similar concentration of BSA, suggesting the protective effect was due to scavenger and non-specific effects. In addition, there was no refolded active enzyme that was immunoprecipitated using protein G immobilized to sepharose, indicating that MAB11 was not associated with the active refolded enzyme. However, the purified antibody was able to inhibit refolding to active enzyme when present in the refolding media to which denatured enzyme was added. The inhibition was dependent on the time at which the antibody was added to the

C-18-88 (continued)

refolding enzyme. As the time of addition of antibody was delayed, the ability to inhibit refolding was reduced. Antibody added after about 5 minutes of refolding had little effect on inhibition of regain of activity, suggesting that the refolding of rhodanese proceeds through a molten globular state in which the MAB11 epitope is expressed but which when MAB11 is bound provides a steric blockade of refolding to an active enzyme. Within minutes, an intermediate enzyme conformation is achieved which is committed to refolding to active enzyme. This intermediate does not express the MAB11 epitope or the subsequent refolding displaces MAB11 from the epitope as the active refolded enzyme is not immunoprecipitated by protein G sepharose.

Subsequent experiments will be to assess the ability of MAB11 to support circular dichroism and intrinsic fluorescent data suggesting that inactive but essentially refolded rhodanese intermediates can be isolated. Production of additional monoclonal antibodies to rhodanese are also intended.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-16-90                      Status: Completed

Title: Evaluation of Central Hemodynamics During the L1 Anti-G Straining Maneuver.

Start date: 18 Jan 90	Estimated completion date:
Principal Investigator: Ricky D. Latham, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$50,340.00 (R&D)

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Evaluate left and right heart blood pressures and flows during two components of the standard L1 anti-G straining maneuver: an abdominal strain and peripheral muscle strain. 2) Measure SVC and IVC flows by noninvasive doppler to determine the effects as a function of time on venous return by this maneuver. 3) Evaluate blood pressure response by noninvasive means in the operational environment with and without straining.

Technical Approach: In part 1 of the study, 10 patients age 20-55 undergoing routine cardiac catheterization will be asked to perform several Valsalva maneuvers. At the same time blood pressure and flow velocity will be recorded. In part 2 of the Study, 10 healthy Army aviators, age 20-55, will be asked to wear a noninvasive portable blood pressure device to record blood pressures during flight in a high performance helicopter. An accelerometer will be used to record the g stresses encountered. A minimum of five flights will be used for the study.

Progress: Data collection/analysis completed. Manuscript has been submitted for review.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-4-91                      Status: Ongoing

Title: Development of a Bioluminescent Assay of Extreme Sensitivity for Detection and Quantitation of Ricin

Start date: 16 Nov 90	Estimated completion date:
Principal Investigator: Gerald A. Merrill, Ph.D	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To develop a solid phase enzyme-linked sandwich assay of high sensitivity for the detection and quantitation of ricin which is based on avidin-biotin technology, enzymatic generation of ATP, and the sensitivity of photon counting detection of ATP via the bioluminescent luciferin-luciferase (firefly).

Technical Approach: A solid phase enzyme linked immunoassay for quantitation of ricin utilizes the chemiluminescence of a luminol derivative which emits light at alkaline pH following the removal of a phosphate group by the action and concentrate the toxin which may be present in very low concentrations. The quantitation of ricin that is immobilized involves addition of biotinylated anti-ricin followed by excess avidin-alkaline phosphatase which binds to biotin very tightly. The quantitation of the alkaline phosphatase can be either colorimetric or can be measured via luminescent methods with increased sensitivity using AMPPD as the substrate.

Progress: A working chemiluminescent assay for ricin has been developed. Standard curves in urine, plasma, and buffer demonstrate the ability to detect ricin with a 2-5 fold increase in sensitivity as compared to a colorimetric alkaline phosphatase assay. However, there appears to be much greater day to day variation in the magnitude of the chemiluminescent response as compared to

C-4-91 (continued)

the colorimetric ELISA. To date, the reason for this variability has not been identified. Because quenching of chemiluminescence and non-specific light generation are both pH sensitive, increased buffering capacity may provide more reproducible results. This will be accomplished by use of higher ionic strength buffers appropriate for the alkaline pH range where chemiluminescent responses are optimized.

Botulism toxin is also a potential warfare threat. Because of its extreme toxicity, detection levels in the pg/ml ranges are required. Thus modifications in the assay for ricin will be attempted to increase the ability to detect ricin with even greater sensitivity that is achieved by the present chemiluminescent ELISA. The modified assay will then be adapted for use in detection of botulism toxin. The proposed modification will be to develop an immuno-PCR assay which uses chemiluminescent detection. Anti-ricin antibodies will be attached to DNA flags. Following capture of ricin in the test samples by use of immobilized anti-ricin antibodies, DNA-labeled anti-ricin antibodies will be allowed to bind to the now immobilized ricin. Polymerase chain reaction amplification of DNA sequences which extend beyond the DNA sequence complimentary to the antibody attached DNA flag will be used to increase sensitivity. One nucleotide of the PCR amplification media will be biotinylated, thus producing heavily biotinylated DNA sequences when PCR amplification is achieved. Bromo-deoxyuridine will also be included in the nucleotide mixture for incorporation in the amplified DNA sequences. Following a specific number of amplification cycles, the amplified DNA sequences will be captured by use of anti-BRDU antibody. Addition of alkaline phosphatase labeled avidin will provide for immobilization of reporter enzyme that can be used to monitor the presence of ricin in the original sample. Detection can be via colorimetric or chemiluminescent detectors depending on the substrate employed.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-10-91                      Status: Terminated

Title: Correlation of Bone Marrow Biopsy Cellularity with Percentage of Nucleated cells Recovered from Autologous Bone Marrow Harvests

Start date: 30 Nov 90	Estimated completion date:
Principal Investigator: Barbara Reeb, MT (ASCP)	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: N/A

Number of subjects enrolled during reporting period: 28

Total number of subjects enrolled to date: 162

Periodic review date:                      Review results:                     

Objective(s): To determine how well the nucleated cell count correlates with the percent cellularity at biopsy.

Technical Approach: This is a retrospective study to determine the relationship between the bone marrow biopsy cellularity reported and the percentage of nucleated cells recovered from the harvested marrow. Using this information it is hoped that a factor can be devised from the cellularity that can "correct" the nucleated cell count so a more accurate estimate of total cells and volume to be withdrawn can be achieved.

Progress: No new data recovered. Will terminate study due to a change in volume collected at harvest. A new disposable set or technique has reduced average volume collected from 1800 ml to 1200 ml and still yielded an adequate cell dose.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-25-91                      Status: Ongoing

Title: Automated Screening of Western Blot Densitometry Scan for the Detection of Type-Specific Herpes Virus Antibodies.

Start date: 6 Feb 91	Estimated completion date: 6 Feb 93
Principal Investigator: John A. Ward, PhD	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Julia K. Hilliard, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the application of digital signal processing techniques and correlation analysis (DSPCA) of Western blot analysis (WBA) densitometry scans can be used to distinguish B virus antibodies from herpes simplex antibodies in human sera.

Technical Approach: 1) Average 30 samples of WBAs to establish density pattern representative of both common and type specific antibodies for: a) HSV1 infected humans, b) HSV2 infected humans, and c) B Virus infected monkeys. 2) Subtract common antibody patterns from unknown WBAs to filter out the effect of cross-reacting antibodies. 3) Correlate type-specific patterns with filtered unknown WBAs and calculate correlation coefficients and standard errors. 4) Classify unknown WBAs on the basis of correlation analysis. 5) Tabulate successful and unsuccessful classifications of HSV1, HSV2, B virus and mixed infections and compare computer and human expert success rates using a contingency test.

Progress: Correlation analysis was found to be inadequate and was replaced with neural network analysis. Preliminary experiments with neural networks indicated a need for a better theoretical understanding of the nature of learning in artificial neural networks. To visualize the solution space of multilayered feed forward artificial neural networks, 2XNXNX2 networks were trained by back propagation to recognize membership in two dimensional sets with quadrangular, circular and annular boundaries. The output was color coded on a graphical display of the XY plane. The RMS error was calculated

C-25-91 (continued)

from observed vs. expected outputs for all points in the training set. As RMS error decreased, the solution space approximated the boundary of the training set. 1) The network learns the set boundary and does not memorize the training set, 2) A training set must represent boundary conditions and 3) Learning rate decreased if the set envelope and/or center is not in the set. The results are generalizable to higher dimensions.



**Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** C-49-91      **Status:** Ongoing

**Title:** The Use of Polymerase Chain Reaction (PCR) to Detect Hepatitis C in Units of Donor Blood

<b>Start date:</b> 9 Apr 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Curtis L. Yeager, MAJ, MS	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department Of Clinical Investigation	<b>Associate Investigator(s):</b> William F. Nauscheutz, CPT, MS Victor Tryon, PhD
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To develop an assay to test for Hepatitis C virus (HCV) in units of donated blood collected at BAMC, using polymerase chain reaction and robotic technology.

**Technical Approach:** We intend to develop methods which combine the technology of robotics and high sensitivity and specificity of the polymerase chain reaction (PCR) to detect Hepatitis C virus (HCV) in approximately 300 units of donor blood daily. We will develop the system such that test results will be available the same day the units are drawn.

**Progress:** We are awaiting the arrival of some equipment ordered.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-58-91                      Status: Ongoing

Title: Preparation of Large and Small Unilamellar Vesicles and Interaction with Magainin

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Earl Grant, Jr., MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish the means and verify the methodology that will produce well-defined liposomes for use as model membranes for the study of protein/peptide-lipid interactions and as potential drug carriers to aid in cancer therapy.

Technical Approach: Large unilamellar vesicles of various lipid compositions will be prepared by the reverse phase ether evaporation method. Small unilamellar vesicles of various lipid compositions will be prepared by sonication. The functional integrity of the vesicles can be assessed by monitoring the release of entrapped 6-carboxyfluorescein in the absence and presence of Triton X-100.

Progress: We maintain the capability to produce small unilamellar vesicles, however, we do not have the equipment to prepare large unilamellar vesicles by the reverse phase ether evaporation method. The needed equipment is being requisitioned and alternative methods are being investigated.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-91-91 Status: Ongoing

Title: Molecular Detection of Bloodborne Pathogens in Blood for Transfusion with Emphasis on Hepatitis C.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, MAJ, MS	Facility: Brooke Army Medical Center
Department/Service: Department of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To develop methods which combine the speed and precision of robotics and the high sensitivity and specificity of gene amplification strategies to detect RNA from the hepatitis C virus in 300 units of volunteer donor blood daily.

Technical Approach: Research in this proposal is designed to adapt gene amplification techniques to a clinical diagnostic format capable of operating at a process level (300 plus tests per day). Research to be conducted includes identification and development of unique nucleic acid probes and primers, testing of amplification techniques, development of solid phase nucleic acid capture assays; adaptation of radiometric assays to machine-read fluorometric testing and side-by-side comparison of the molecular diagnostic assays developed versus the standard serological assay.

Progress: This study is still pending approval of research funding by Medical Research and Development Command.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-20                      Status: Ongoing

Title: Establishment of a Polymerase Chain Reaction (PCR) Nucleic Acid Amplification capability Within the Department of Clinical Investigation, BAMC

Start date: Feb 93	Estimated completion date: Feb 95
Principal Investigator: Curtis L. Yeager, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): N/A
Key Words: Polymerase chain reaction Taq polymerase, Ethidium bromide Agarose gel electrophoresis	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: Approved \$2725.00                      Used \$1457.01

Number of subjects enrolled during reporting period: N/A  
 Total number of subjects enrolled to date: N/A  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish a working PCR gene amplification capability. It will result in the capability to specifically amplify a positive control bacteriophage gene without contamination by irrelevant nucleic acids. Demonstration of the desired product will include separation of the amplification products by agarose gel electrophoresis and identification by product size as seen after ethidium bromide staining.

Technical Approach: No subjects involved. Controls for the reaction are contained within the kits and include a distilled water negative control and a specific bacteriophage gene positive control. Experimental design/methods; data collection and details included in protocol.

Progress: The initial PCR was successfully accomplished and resulted in the contamination-free amplification of a Lambda bacteriophage gene. Continuing to optimize those reactions as well. Analysis of amplification products by agarose gel electrophoresis and ethidium bromide staining has been successful and both this and PCR are being taught to DCI staff.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-95      Status: Ongoing

Title: Inoculation with Pentavalent (ABCDE) Botulinum Toxoid

Start date: 16 Jul 93	Estimated completion date:
Principal Investigator: James M. Lamiell, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Dec 93      Review results: \_\_\_\_\_

Objective(s): Immunization of one volunteer who will be working with botulism toxin at Fort Detrick, MD.

Technical Approach: The vaccine will be obtained from the centers for Disease Control (CDC). The initial vaccination series will be given 0.5 ml deep subcutaneously at 0, 2, and 12 weeks. Forty-eight hours after each injection, the injection site will be observed by the principal investigator. The first booster will be given 0.5 ml deep subcutaneously 12 months after the first injection of the initial series. Subsequent boosters will be given 0.5 ml deep subcutaneously at 2 year intervals, based on antitoxin titers. Any reactions or side effects will be observed and reported to the CDC.

Progress: One subject has received the initial series of 3 immunizations, given as 0.5ml deep subcutaneous doses at 0, 2 and 12 weeks. No adverse reactions have been noted. Neutralization titers developed from the initial immunization series will be determined at Salk Institute using serum obtained 28 days following the 3rd immunization dose.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** C-105-90      **Status:** Ongoing

**Title:** Evaluation of Prophylactic Dicloxacillin in Cat Bite and Cat Scratch Wounds.

<b>Start date:</b>	<b>Estimated completion date:</b> Aug 93
<b>Principal Investigator:</b> Marc Daymude, CPT, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Emergency Medicine	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 2  
**Total number of subjects enrolled to date:** 2  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine if prophylactic treatment of cat bite and cat scratch wounds reduces the rate of infection.

**Technical Approach:** The study population will consist of 100 adult patients who have received cat bites within four hours of presenting to the Emergency Department. The study will use a randomized, double-blinded protocol to compare treatment with dicloxacillin to amoxicillin/clavulanate to placebo. All patients will be seen again 24-72 hours after initial presentation and will be called at home at the completion of the study. The percentages of infected wounds in the three groups will be compared using the chi-square test.

**Progress:** Data analysis is in progress but not yet finalized.

### Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: C-92-12

Status: Completed

Title: The Prevalence of Pneumococcal Vaccination among High Risk Patients Presenting to Military Emergency Departments

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Rodgers, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To assess vaccination prevalence in those high risk groups presenting at two major military Emergency Departments. 2) To address the utilization of the Emergency Department as part of a strategy for increasing adult immunization. 3) To compare the differences, if any, between military and a single civilian institution (already studied), and, 4) To compare pneumococcal vaccination prevalence differences, if any, between a major US Air Force and US Army Medical Center.

Technical Approach: Study proposed would consist of a single questionnaire. The question sheet will be distributed by the charge nurse to every patient entering the ED. Each care provider involved would be given guidelines on use of the pneumococcal vaccine. The decision to administer the vaccination would be based on 1) the patients' acceptance, 2) the patients medical condition as determined by the physician providing care in the Emergency Department at the time of presentation. Whether or not the vaccine was administered will be recorded and analyzed.

Progress: Data collection completed. Results have been published at SAEMS.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-32                      Status: Completed

Title: The Use of Eye Patching in the Treatment of Corneal Abrasion

Start date:	Estimated completion date:
Principal Investigator: MAJ Henry E. Halloway, Jr., MC	Facility: Brooke Army Medical Center
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Proposed study is a multi-center randomized prospective evaluation of corneal epithelial defect healing, evaluating the use of double eye patching. This study will also compare discomfort and visual impairment with each of the two treatment plans.

Technical Approach: After appropriate history and ocular examination (visual fields, visual acuity, fluorescein staining, ophthalmoscopic and slit lamp) those patients with corneal epithelial defects and without any complicating lesion to any other parts of the eye will be asked to participate in the study.

Progress: Study completed. Currently awaiting results of data analysis.



# Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-50

Status: Completed

Title: Technical Competence in Echocardiography

Start date:	Estimated completion date:
Principal Investigator: CPT Lou Anne Wellford, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): MAJ Landon Wellford, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20

Total number of subjects enrolled to date: 20

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the ability of Emergency Medicine physicians to recognize pericardial effusions by echocardiography (echo) and to compare their performance before and after a brief training session.

Technical Approach: a) Subject Selection: Test subjects will consist of ten staff Emergency Medicine physicians and ten upper level Emergency Medicine residents (third and fourth post graduate years). b) Patient Selection: Patients with one of the following findings documented by echo will participate: 1) Normal control-i.e., no pericardial/pleural effusions. 2) Small pericardial effusion. 3) Moderate pericardial effusion. 4) Pleural effusion.

Progress: Study completed. Twenty subjects tested. Overall trend toward improvement in detecting pericardial effusions. Further statistical analysis not possible secondary to study design.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-40                      Status: Ongoing

Title: An Evaluation of Nafcillin for the Initial Treatment of Cellulitis

Start date: 24 Dec 92	Estimated completion date:
Principal Investigator: Curtis Hunter, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): Kevin Rodgers, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 36  
 Total number of subjects enrolled to date: 36  
 Periodic review date:                      Review results:                     

Objective(s): To evaluate the effectiveness of oral antibiotics in treating cellulitis and preventing subsequent admission of patients with cellulitis. Compare the efficacy of an initial parenteral dose of antibiotics in preventing the subsequent admission of patients with cellulitis, as compared to those patients who do not receive parenteral antibiotics. Compare the efficacy of an initial dose of parenteral antibiotics in treating more rapidly those patients with cellulitis, as compared to those patients who do not receive antibiotics.

Technical Approach: This will be a randomized, prospective study. Patients with cellulitis deemed appropriate for outpatient therapy will be randomized at the beginning of the study to one of two treatment regimens. Patient eligibility, exclusion criteria and study plan outlined in protocol.

Progress: No treatment failures to date.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-60-86                      Status: Ongoing

Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start date: 25 Jun 86	Estimated completion date:
Principal Investigator: C. Kenneth McAllister, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s):
Key Words: HTLV-III	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50 new  
 Total number of subjects enrolled to date: 500  
 Periodic review date: n/a                      Review results: \_\_\_\_\_

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.).

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for Future testing.

Progress: The study continues; approximately 500 patients have been enrolled. Again, his is a descriptive study of Army HIV patients and the clinical cause of their HIV infection.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-52-87                      Status: Ongoing

Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex Vivo Marrow Treatment with 4-hydroxyperoxycyclophosphamide (4-HC).

Start date: 13 May 87	Estimated completion date:
Principal Investigator: Svetislava J, Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: Study ongoing for eligible patient enrollment.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-62-87                      Status: Ongoing

Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol).

Start date: 25 Jun 87	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Robert G. Whiddon, Jr, LTC, MS Barbara Reeb, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$19,404.00

Number of subjects enrolled during reporting period: 39  
Total number of subjects enrolled to date: 206  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion. (This is the master protocol for the autologous bone marrow transplant program.

Progress: Study remains ongoing for eligible patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-64-87                      Status: Ongoing

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance.

Start date: 21 Jul 87	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 48  
 Periodic review date: 19 Oct 92      Review results: Continue

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evaluation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a  $\dot{V}_{D_{CO}}$ , cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GM stains; 2) culture for AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4)

C-64-87 (continued)

quantitation of lymphocytes, PMNs, monocytes as well as lymphocyte subsets particularly OKT4 and OKT8.

Progress: No new patients have been added during the review period.

### Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-11-88 Status: Ongoing

Title: Effect of Thyroid Replacement on Lipid Profile - Differences Associated with Keeping the TSH in Low Normal as Compared to Upper Normal Euthyroid Range.

Start date: 2 Dec 87	Estimated completion date:
Principal Investigator: Department of Medicine/Endocrinology	Facility: Brooke Army Medical Center, Texas
Department/Service: Albert M. Thomason, COL, MC	Associate Investigator(s):
Key Words: Euthyroid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 3  
Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To demonstrate a difference in the lipid profile of euthyroid patients treated with higher or lower doses of thyroid replacement therapy.

Technical Approach: Patients being treated with thyroid replacement are enlisted as volunteers. Individual patients have their TSH levels adjusted by varying their thyroid replacement dose to above 3.5 mIU or below 1.1 mIU/ml depending on whether the initial value was above or below the mean euthyroid value of 2.3 mIU/ml. The patient is maintained at the lower or higher TSH value for 3 months as determined by monthly measurements. Then, the patient's serum lipid profile (cholesterol, triglyceride, and HDL cholesterol) is determined after a 14 hour fast x 2. Subsequently, the patient has his dosage of thyroid replacement adjusted to keep his TSH value in the opposite end of the euthyroid range from which it was initially. After three months of stabilization of the new value of TSH level, the plasma lipid profile is repeated. Subsequently, the patient again has his TSH value adjusted to a relatively higher or lower value depending on where he started initially. After another 3 month period of stabilization, lipid profile is obtained again.

Progress: We are still experiencing a lack of volunteers. More effort will be made to recruit volunteers.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-19-88                      Status: Ongoing

Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: Albert M. Thomason, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 19 Mar 91      Review results: Continue

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type I diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profile while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: We are still lacking in recruitment of volunteers. More effort will be made to recruit volunteers which as stated previously is very difficult without being able to provide some kind of compensation.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-47-88                      Status: Ongoing

Title: Percutaneous Recanalization of Human Coronary Arteries with Balloon-Expandable Intracoronary Grafts (BEIG). (Collaborative Study with University of Texas Health Science Center)

Start date: 25 Apr 88	Estimated completion date:
Principal Investigator: William Wright, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23  
 Total number of subjects enrolled to date: 29  
 Periodic review date: 25 May 91      Review results: Continue

Objective(s): 1) To determine the safety of the stent by evaluating reporting clinical complications associated with its placement. 2) To determine the effectiveness of the stent by evaluating patients for long-term patency rates. Patency will be compared with results reported in the literature for PTCA alone. In addition, results will be compared with follow-up of a concomitant group of control patients treated by PTCA.

Technical Approach: This study is designed as a prospective survey following placement of a Balloon Expandable Intracoronary Stent in a coronary artery. The stent will initially be implanted in patients with confirmed collateral blood flow to the distal portion of the stenotic coronary artery.

Progress: This study has been reassigned to another principal investigator. There is no data to report at this time.

# Detail Summary Sheet

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Date: 15 Dec 93                      Protocol Number: C-23-89                      Status: Ongoing

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Title: Retrospective Analysis of Acute Exacerbations of Chronic Renal Failure.

Start date: 27 Jan 89	Estimated completion date:
Principal Investigator: Steven F. Gouge, MAJ MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

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Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 212  
 Periodic review date: 3 Feb 93                      Review results: \_\_\_\_\_

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Objective(s): To determine the risk factors for, clinical presentations and outcomes of acute exacerbations of chronic renal failure; and to compare these variables in patients to patients with chronic renal failure without exacerbation and patients with acute renal failure without prior chronic renal failure.

Technical Approach: Records of patients with a discharge diagnosis of acute renal failure, CRF, or both during the period 1986 and 1987 will be reviewed.

Progress: Data analysis has been completed. Individual is working on manuscript preparation. No change in status as of this date.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-63-89                      Status: Ongoing

Title: What is the Value of Fecal Hemoccult Blood Tests Performed at the Time of Digital Rectal Examination

Start date: 26 Apr 89	Estimated completion date:
Principal Investigator: Shailesh Kadakia, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): MAJ Charles Cohan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$750.00

Number of subjects enrolled during reporting period: 89  
 Total number of subjects enrolled to date: 37  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): To determine the clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult Method) discovered at the time of routine digital rectal examination.

Technical Approach: Adult patients over the age of 40 with positive hemoccult tests obtained on normal appearing stool obtained at rectal examination are eligible. Patients are offered the standard care which includes full evaluation of the lower GI tract and possibly of the upper GI tract. Stool Hemoccult II samples are collected on 3 consecutive days in the usual manner with standard dietary and drug restrictions. Hemoquant assays to determine the total amount of hemoglobin in the stool is also determined on the same stool samples. Findings at colonoscopy and/or upper endoscopy are noted.

Progress: Since the initiation of the study in April 89, a total of 89 patients have been entered into the study. Patients have been referred to us from various clinics to include Internal Medicine, OB-GYN, Urology, and Physical Examination Clinics. Patients have been enrolled from two centers, Brooke Army Medical Center and Tripler AMC. Group A included 75 patients with both negative Hemoccult and negative Hemoquant. There were a total of 75 patients in this group. Lesions were found in 28 of 75 patients and included colonic polyps in 19, AV malformations in 2, gastric ulcer in 3, lipoma in 2,

C-63-89 (continued)

gastric polyp in 1, and gastric erosions in 5. Of the 19 colonic polyps, 18 were less than 1cm, and 1 was equal to or greater than 1cm. 25 patients were taking aspirin or NSAIDs at the time of digital rectal exam.

Group B consisted of 5 patients with only Hemoccult positive stools, 4 patients with only Hemoquant positive stools and 5 patients who had both Hemoccult and Hemoquant positive. There were 14 patients in this group. Lesions were found in 12 of the 14 patients and included colon cancer in 2, colonic adenomas with severe dysplasia in 2, colon polyps in 6, AV malformations in 1, and gastric ulcer in 3. 5 patients in this group were taking aspirin or NSAIDs at the time of digital rectal exam. In both groups, gastric ulcer and gastric erosions were common in those patients taking aspirin or NSAIDs.

In conclusion, most patients with positive fecal occult blood at routine digital rectal exam have both negative Hemoccult and Hemoquant on subsequent stool testing. Aspirin and NSAIDs probably account for most of the false-positive fecal occult blood tests at routine digital rectal exam. Significant number of patients with positive Hemoccult and/or Hemoquant have lesions compared to those with negative Hemoccult and Hemoquant. In addition, lesions found in patients with positive Hemoccult and/or Hemoquant are also clinically more significant and serious.

There appears to be no significant advantage of hemoquant over hemoccults in detecting the true positive cases. There appears to be no significant pathology found at colonoscopy or upper endoscopy in patients who do not have evidence of blood on three hemoccult cards. It appears that there is a trend in finding pathology in patients who show presents of blood during subsequent testing using the hemoccults or hemoquant.

There was one patient who had colitis after a colonoscopy the full report and followup of this patient was submitted to the Clinical Investigation Department for their review. There seems to be no need for revision of the protocol and we intend to continue the study as has been outlined in the past. Our final report will be provided as soon as the data is analyzed in its final form which we expect to end in the next four to six months.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-103-89                      Status: Terminated

Title: Single Patient Protocol for Treatment of Systemic Mycoses with Itraconazole (R51,211).

Start date: 2 Aug 89	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL. MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Sep 91      Review results: Continue

Objective(s): Compassionate use of drug Itraconazole for treatment of systemic mycoses.

Technical Approach: Eligible patients must have positive culture and/or histologic findings which identify the pathogen. Dosage will be initiated on 100 mg qd with a meal and maintained on that dose for at least a month. If patient is unchanged or worsening, dose may be increased in 100 mg increments to a maximum of 400 mg/day. The optimal duration of treatment is unknown, but a treatment course of about one year is planned.

Progress: A single patient was enrolled and treated without complication. The compassionate use protocol was terminated with the market release of itraconazole.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-107-89                      Status: Ongoing

Title: Phase I Trial of Intrapleurally Administered Alpha Interferon in Malignant Pleural Effusions.

Start date: 14 Aug 89	Estimated completion date:
Principal Investigator: Howard A. Burris, III, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 13 BAMC  
 Periodic review date: thru 31 Dec 93      Review results: Continue

Objective(s): 1) To determine the tolerance to and toxicity of intrapleural administration of Intron-A in patients with malignant pleural effusions.

2) To determine antitumor activity of Intron-A intrapleurally as evidenced by control of pleural effusions.

Technical Approach: Treatment of eligible patients will follow the schema outlined in the study protocol.

Progress: Toxicity consists of mild flu-like symptoms being observed at the current dose level of 50 million units/m2. Anticipate closure at this dose level after enrollment of another 2-4 patients.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-122-89                      Status: Terminated

Title: A Technique for the Growth of Epidermal Sheets Obtained from Patients Undergoing Reduction Mammoplasty.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator Jerome C. Hill, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Dermatology	Associate Investigator(s): Ronald E. Grimwood, LTC, MC, USAF Larry E. Becker, COL, MC William K. Becker, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$31,500.00 (R&D)

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: 10 Sep 90      Review results: Continue

Objective(s): To establish a technique for isolating and growing epidermal sheets from cells obtained from patients undergoing reduction mammoplasty.

Technical Approach: Discarded skin was obtained from patients undergoing reduction mammoplasty. The epidermis was enzymatically separated from the dermis. Keratinocytes were isolated from the epidermis and seeded in 25 cm<sup>2</sup> cell culture flasks. The growth medium was Keratinocyte Growth Medium (KGM) which has been developed for the growth of keratinocytes. In approximately two weeks, the primary keratinocyte cultures were nearly confluent and were serially subcultured to expand the volume of cells.

When secondary cultures reached confluence, the cell medium was changed to Dulbecco's Modified Eagles' Medium containing 10% fetal calf serum. The change to a medium containing serum and a higher calcium concentration induced the keratinocytes to stratify into multi-layered sheets. These epidermal sheets were removed from the culture flask with Dispase, a neutral protease, and attached to petrolatum gauze. At this point the sheets could be used as skin grafts.

Progress: Principal investigator has PCS'd and efforts to contact him have been unsuccessful. There has been no action on this protocol by associate investigators. Study is terminated.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-3-90                      Status: Ongoing

Title: Differences in Response to Thiazide-Induced Hyponatremia by Gender.

Start date: 7 Dec 89	Estimated completion date: Jun 94
Principal Investigator: MAJ Kevin C. Abbott, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s): Steven F. Gouge, MAJ, MC Daniel Gavin, CPT, MC
Key Words: Hyponatremia, gender, thiazides, free water clearance, antidiuretic hormone	
Cumulative MEDCASE cost: \$4800	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 9  
 Periodic review date: n/a                      Review results: \_\_\_\_\_

Objective(s): To determine the differences, if any, between healthy elderly males and females in response to a water challenge test before and after the administration of hydrochlorothiazide.

Technical Approach: Eight men and eight women (power analysis projections from current results allowed this change from the original estimate of ten men and ten women), age 55 and above, with no concurrent hypertension or diabetes will be studied. Baseline blood tests will be drawn for serum sodium and potassium levels as well as thyroid function tests and a baseline water challenge test in which they will drink 20 cc/kg of ideal body weight of fresh water followed by a four hour timed urine collection for urine electrolytes and osmolality. Before the water load and after four hours, blood samples will be drawn for serum sodium, potassium, antidiuretic hormone, prolactin, diuretic levels and atrial natriuretic factor.

Progress: Seven of the projected sixteen subjects have been studied. Dr. Gavin, a medicine resident, will be participating in the study as his official research project. The cost of the antidiuretic hormone assay at Nichol's lab has increased considerably since the beginning of the study and would increase the cost of the study to \$9800 for the number of samples required. We are in

C-3-90 (continued)

the process of surveying other potential avenues for obtaining this assay. There have been no complications, misadventures or adverse reactions associated with this study to date.

Detail Summary Sheet

Date: 31 December 93 Protocol Number: C-21-90 Status: Ongoing

Title: A Double Blind Clinical Evaluation of the Safety and Efficacy of Fenticonazole Cream (2% Fenticonazole Nitrate) in treatment of Tinea Pedis.

Start date: 25 Jan 90	Estimated completion date:
Principal Investigator: Larry E. Becker, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Dermatology	Associate Investigator(s): Richard A. Keller, MD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40  
Total number of subjects enrolled to date: 40  
Periodic review date: Review results:

Objective(s): To determine the safety and efficacy of Fenticonazole Cream in the treatment of tinea pedis.

Technical Approach: Approximately 40 patients will be selected for participation in this study. Male and female patients eighteen years of age and older with clinical signs of moderate to severe tinea pedis will be treated for four weeks once daily with vehicle controlled placebo or active agent. Follow-up visits at 2 and 4 weeks and again at 6 weeks (2 weeks after completing treatment) will be used to evaluate clinical and laboratory evidence of success of therapy.

Progress: Study remains open for patient accrual for clinical/laboratory evaluation of effectiveness of therapy.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-22-90 Status: Ongoing

Title: Phase II Clinical Trial of Anagrelide in Thrombocytosis of Myeloproliferative Disorders (70014), Compassionate Use.

Start date: 25 Jan 90	Estimated completion date:
Principal Investigator: COL Timothy J. O'Rourke, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To determine the ability of anagrelide to effectively reduce platelet numbers in patients with thrombocythemia, to determine the dose of anagrelide which would be required to reduce platelet numbers and the dose needed to maintain them at or close to normal levels and to evaluate the safety of this compound.

Technical Approach: As outlined in the protocol.

Progress: A single patient continues enrolled on this study. He has experienced no adverse side effects and is doing well.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-24-90 Status: Ongoing

Title: Induction of TNFa and IL-1 in Human Tuberculosis.

Start date: 5 Feb 90	Estimated completion date:
Principal Investigator: Gregg T. Anders, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary Disease	Associate Investigator(s): J. William Kelly, MAJ, MC C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$18,300.00 (R&D)

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): The objective of this study is to determine the extent of tumor necrosis factor-alpha (TNF-a) and interleukin-1 (IL-1) production association with human tuberculosis. Peripheral blood monocytes cells (PBMC) from patients with positive purified protein derivative (ppd) skin reactions or active tuberculosis will be compared with healthy controls (PPD negative) by in vitro stimulation with mycobacterial antigens and killed Mycobacterium tuberculosis and the concurrent production of TNF-a and IL-1 measured by ELISA.

Technical Approach: Patients and healthy controls (staff volunteers) will be phlebotomized approximately 50 ml of blood by peripheral venipuncture. In vitro antigen stimulation of PBMC and measurement of TNF-a and IL-1 production by ELISA will be performed.

Progress: Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-29-90 Status: Completed

Title: Epsilon-aminocaproic Acid Mouthwash Therapy For Dental Extraction of Lower Molar Teeth in Normal Subjects: A Double Blind Controlled Trial.

Start date: 13 Feb 90	Estimated completion date:
Principal Investigator: William Nickel, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/General Medicine	Associate Investigator(s): Williams P. Mills, Jr., LTC, DC Andrew A. Vorana, LTC, DC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 112  
 Total number of subjects enrolled to date: 237  
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To conduct a randomized, double blind placebo controlled trial to evaluate the effect of low-dose EACA as a mouthwash on the incidence of dry socket in the general population.

Technical Approach: Patients will be randomized to receive either EACA solution placebo (the same solution without EACA). This solution will be used to wash the extraction site and soak the dressing placed at the end of the procedure. A supply of the solution will be given along with instructions to use two tablespoons to swish in the mouth for 2 minutes. This will be done 6 hours after the procedure and then three times a day for 4 days. Three days and seven days after the procedure, the participant will be contacted to determine if there is any pain, how well they are able to eat, and any other problems the ma be having. If there is any indication of dry socket they will be asked to return.

Progress: Study complete. Data being correlated with Hematology/Oncology.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-40-90                      Status: Ongoing

Title: Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: William G. Wortham, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 3 Feb 93      Review results: Continue

Objective(s): To determine if prostaglandins are diminished in response to radiocontrast administration in the human subject. Further to determine if the decrement, if noted, correlates with a change in renovascular resistance, renal blood flow and/or creatinine clearance during the acute period surrounding radiocontrast administration.

Technical Approach: Participants will be admitted 24 hours prior to cardiac catheterization for collection of a 24-hour urine sample for sodium and prostaglandin metabolites, thromboxane B2 and 24-hour creatinine. In addition, they will undergo a nuclear determination via plasma clearance, I<sup>131</sup> Hippuran and DTPA to determine renal blood flow as well as GFR via radionuclide study 4-6 hours prior to catheterization, they will receive half-normal saline at approximately 125 cc/hour if not contraindicated by volume status. At cardiac catheterization, a determination of central venous pressure will be necessary. immediately after contrast administration, a second spot renin and catechol determination will be made. After cardiac catheterization a 24-hour urine will be collected for prostaglandin metabolites and sodium and creatinine as well as routine serum creatinine and electrolytes. An I<sup>131</sup> Hippuran and DTPA for determination of renal plasma flow and glomerular filtration will be obtained 24 hours post cardiac catheterization.

Progress: Study ongoing but still has not been actively pursued due to time

C-40-90 (continued)

constraints of myself, Nuclear Medicine Service and significantly by inability to recruit patients from the Cardiology Service. No other changes.



# Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-63-90

Status: Terminated

Title: Comparison of Adenosine, Dipyridamole, and Dobutamine Stress Echocardiography.

Start date: 15 May 90

Estimated completion date:

Principal Investigator:  
Timothy Martin, MAJ, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department Medicine/Cardiology

Associate Investigator(s):  
John Seaworth, LTC, USAF, MC  
Joseph Johns, MAJ, MC  
Lawrence Pupa, MAJ, MC  
Williams Condos, LTC, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8

Total number of subjects enrolled to date: 40

Periodic review date: Review results:

Objective(s): To compare the ability of adenosine (AD), dipyridamole (DI), and dobutamine (DO) echocardiography to detect coronary vascular disease and compare the incidence and degree of adverse effects following adenosine, dipyridamole and dobutamine administration.

Technical Approach: We compared AD, DI, and DO stress echo in 32 patients. Each received intravenous AD, DI, and DO in a single-blind random order. Two dimensional echocardiography was positive if abnormal wall motion was present at rest or during infusion. Coronary angiography was performed within six weeks of testing. Eight patients had single vessel disease (stenosis > 50%) and 16 patients had multivessel disease. Thirteen were taking beta blockers and 22 calcium channel blockers.

Progress: Study terminated.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-65-90 Status: Terminated

Title: Treatment of Chronic Cutaneous Ulcers with Cultured Epidermal Autografts.

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Jerome C. Hill, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Dermatology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine the suitability of autologous keratinocyte grafts for treatment of chronic cutaneous ulcers which have been refractory to standard therapy.

Technical Approach: Keratinocytes will be isolated from a small skin biopsy. The cells will be grown into stratified sheets and will be transplanted back to the patient from which the cells were obtained. The hypothesis to be tested: Can cutaneous ulcers which have not healed in spite of standard therapy be stimulated to epithelialize by using cultured epidermal autografts, even if the ulcer's base is the cortex of an underlying bone?

Progress: Exact status of study is uncertain. Dr. Hill PCS'd from BAMC and efforts to contact him have been unsuccessful.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-71-90                      Status: Ongoing

Title: High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 11  
 Periodic review date: 20 Sep 91 Review results: Continue

Objective(s): To determine the toxicity, time to marrow reconstitution, responsive rate, and time to treatment failure of high-dose combination chemotherapy with carboplatin, etoposide, and cyclophosphamide followed by autologous marrow infusion in eligible patients with advanced metastatic solid tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains ongoing for patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-77-90                      Status: Terminated

Title: The Effect of Early versus Delayed Entry of Coronary Artery Bypass Graft (CABG) Patients into a Cardiac Rehabilitation Program on Selected Measures of Cardiac Function, Cholesterol Levels, and Quality of Life.

Start date: 19 Jul 90	Estimated completion date:
Principal Investigator: Stacey Adams Dramiga, M.A.	Facility: Brooke Army Medical Center, Texas
Department/Service: Cardiology/Cardiac Rehabilitation	Associate Investigator(s): Antoinette Trafford, MAJ, AN James M. Gilman, LTC, MC Jean Johnson, PhD, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): a) Examine the relationship between time of entry into a cardiac rehab program and measures of physiologic stress, cardiac functioning, cholesterol levels, and quality of life in patients who have had coronary artery bypass graft surgery; b) evaluate the physiological outcomes of CABG patients at six weeks in a cardiac rehab program compared to the same measures after twelve weeks in the program; c) determine the effectiveness of a discharge instruction program of self-regulated activity compared to a comprehensive cardiac rehabilitation program.

Technical Approach: Subjects will be randomly assigned to Group I, entry into the program within 2 weeks after Hospital discharge and Group II, entry into the program 6 weeks after hospital discharge. A third group who live too far from BAMC to attend the Cardiac Rehabilitation Program but will be returning to BAMC for follow-up care will be used as a comparative group. All subjects will receive the same instruction on coronary risk factors, exercise and diet prior to discharge and will maintain a daily record of exercise conducted at home. Measures will be obtained on the four variables of interest prior to hospital discharge, after 6 weeks and 12 weeks in a Cardiac Rehabilitation Program (Groups I and II), and at 6 and 12 weeks post-hospital discharge (Group III).

Progress: Study terminated due to lack of patients.

# Detail Summary Sheet

Date: 15 December 93      Protocol Number: C-78-90      Status: Terminated

Title: Can Transesophageal Echocardiographic Screening for left Atrial Thrombi Preclude Routine Anti-Coagulation of Patients with Atrial Fibrillation before Cardioversion?

Start date: 19 Jul 90	Estimated completion date:
Principal Investigator: Armistead L. Wellford, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): David M. Mego, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Current medical practice dictates routine anticoagulation of patients with nonvalvular atrial fibrillation existing for three or more days prior to cardioversion. This exposes all patients, including those felt to be at low risk for embolus, to the risks of anticoagulation with Coumadin. We hypothesize that the use of transesophageal echocardiography in screening for the presence of atrial thrombi would preclude the need for routine anticoagulation in these patients.

Technical Approach: Patients with atrial fibrillation who are candidates for cardioversion will be randomized to treatment with (standard therapy group) or without Coumadin (experimental group) if the initial transesophageal echocardiogram shows no evidence of intra-cardiac thrombi. After 3 weeks, a repeat transesophageal echocardiogram will be done in order to judge the efficacy of Coumadin in resolving thrombi that may have been observed initially, and to examine the frequency of development of new atrial thrombi while treated or untreated with anticoagulants. After the second transesophageal echocardiogram, all patients without evidence of intra-cardiac thrombi would undergo cardioversion using oral antiarrhythmic agents and/or electrical cardioversion.

C-78-90 (continued)

Progress: A patient entered the protocol and was randomized to TEE. This was read by two staff cardiologists as adequate without evidence of thrombus. He was successfully cardioverted. Later he suffered a CVA. The design was reviewed and felt to be flawed. I called the principal investigator (PI) and withdrew BAMC from the protocol. The study design was reviewed by the PI with similar conclusions and the study was terminated. All data has been collected and turned in to the PI.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-90-90                      Status: Ongoing

Title: Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC Purging in Acute Myelocytic Leukemia (ACL) and Acute Lymphocytic Leukemia (ALL).

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 4

Periodic review date: 1 Oct 92                      Review results:

Objective(s): To determine the effects of autologous transplantations with 4-HC-treated marrow on hematopoietic reconstitution, actuarial relapse rate, and leukemia-free survival in pediatric and adult patients (< 65 y/o) with AML in second or third remission, and ALL in second or third remission.

Technical Approach: Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains ongoing for accrual of patient data.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-93-90                      Status: Completed

Title: Serum Alpha Transforming Growth Factor Activity in Patients with Squamous Carcinoma of the Head and Neck.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Don Shaffer, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s): Howard A. Burris, III, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: thru 31 Dec 93      Review results: Closed

Objective(s): 1) To determine the levels of serum and urine Alpha-TGF prospectively in patients with squamous head and neck cancer.

2) To determine if urine and serum levels of Alpha-TGF correlate with disease stage in patients with squamous head and neck cancer.

3) To determine if surgical removal of squamous head and neck cancer will result in a decrease in serum and urine Alpha-TGF.

Technical Approach: Blood and urine samples will be obtained and evaluated Alpha-TGF.

Progress: This study is completed. The assay for assessing Alpha TGF is being revamped. Future trials will be considered.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-107-90                      Status: Completed

Title: Comparison of Foley Catheter with Standard Replacement Percutaneous Endoscopic Gastrostomy Tube: A Randomized Trial.

Start date: 10 Oct 90	Estimated completion date:
Principal Investigator: Michael A. Cassaday, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shaliesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy and safety of Foley catheter as a replacement gastrostomy tube with commercial replacement gastrostomy tube in prospective randomized trial.

Technical Approach: Approximately 100 ptients will be studied consisting of two groups of 50 patients each, randomly assigned to receive either an all silicon Foley catheter or an all silicone standard commercial replacement kit. All patients who have a PEG will be offered enrollment in the study. All patients who require replacement of deteriorated or malfunctioning PEG tube will be the smaller group. The majority of the patients will have had a PEG placed for at least 4 weeks and have a mature tract between skin and the stomach. The initially placed PEG will be removed and replaced with either a Foley or a standard replacement tube. All ptients will be randomized to either a Foley catheter or a standard replacement tube based on a computer generated randomization.

Progress: Forty-six patients with percutaneous endoscopic gastrostomy who required replacement gastrostomy tube were randomized to either all silicon Foley catheter or Flexiflow commercial replacement gastrostomy tube. There were 24 patients randomized to Foley group, and 22 patients randomized to

C-107-90 (continued)

commercial replacement gastrostomy tube. Plastic ring and retention disc were placed over the foley catheter as well as over the commercial placement gastrostomy tube primrily to prevent proximal migration of the tubes. Patients were given either intermittent bolus feedings or continuous feedings. Tubes C-were flushed after each feeding or at every 4 hours or prn basis after having given medications through the tube. Patients were then followed in the clinic at 2 and 4 weeks and thereafter at 8-12 week intervals.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-108-90 Status: Completed

Title: Phase I-II Trial of Hydroxyurea Using an Oral Intermittent Schedule in Patients with Squamous Carcinoma of the Head and Neck.

Start date: 24 Oct 90	Estimated completion date:
Principal Investigator: Howard M. Burris, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 4 BAMC; 19 UTHSCSA  
 Periodic review date: thru 31 Dec 92 Review results: Continue

Objective(s): 1) To determine the qualitative and quantitative toxicities of Hydroxyurea given orally in a intermittent schedule every 3 days in patients with recurrent or metastatic squamous cell carcinoma of the head and neck.  
 2) To determine the maximum tolerable dose in patients with recurrent or metastatic squamous cell carcinoma of the head and neck using this schedule.  
 3) To determine the response rate of hydroxyurea in patients with recurrent or metastatic squamous cell carcinoma of the head and neck using this schedule.  
 4) To characterize the pharmacokinetics/pharmacodynamics of hydroxyurea on this schedule.

Technical Approach: In order to be eligible for this study patients must have a histologically proven squamous cell carcinoma of the head and neck region that has persisted or recurred following definitive surgery and/or radiation therapy, and is not curable by other forms of therapy. Patients with metastatic disease are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Study completed with MTD of 140g/kg and DLT of myelosuppression. Objective response rate was low at approximately 10%. No additional plans at present for hydroxyurea in this disease type.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-5-91 Status: Completed

Title: A Survey of Gastrointestinal Ulcerations for the Presence of Cytomegalovirus.

Start date: 23 Nov 90

Estimated completion date:

Principal Investigator:  
Allan L. Parker, LTC, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department Medicine/Gastroenterology

Associate Investigator(s):  
Allan L. Parker, LTC, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25

Total number of subjects enrolled to date: 25

Periodic review date: Review results:

Objective(s): 1) To determine the overall prevalence of cytomegalovirus in ulcers of presumed acid-pepsin origin by endoscopic biopsy with immunofluorescent staining and viral cultures.

2) To establish whether a variable in endoscopic appearance presentation, or clinical course is useful in differentiating cytomegaloviral vs. acid mediated ulcer disease.

Technical Approach:

Progress: All biopsies in 38 patients failed to document any evidence of CMV by light microscopy, viral cultures and monoclonal antibody testing. We concluded that cytomegalovirus infection is not a significant factor in routine peptic or NSAID-induced ulcer disease and the discovery of CMV inclusions in gastroduodenal ulcerations should lead to a search for an immunocompromised state.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-11-91 Status: Ongoing

Title: The Effect of Oxygen Breathing Upon Lung Machines in Patients with Emphysema.

Start date: 3 Feb 93	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Pulmonary	Associate Investigator(s): Kevin Kimke, CPT, MC Wayne Honeycut, MAJ, MC H.M. Blanton, MAJ, MC Gregg T. Anders, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40  
 Total number of subjects enrolled to date: 58  
 Periodic review date: 19 Oct 92 Review results:

Objective(s): To study the effects on lung mechanics of breathing 50% oxygen balance nitrogen versus breathing 21% oxygen balance nitrogen in a group of emphysematous patients with moderately severe disease.

Technical Approach: Patients undergo forced vital capacity, thoracic gas volume, airway resistance and compliance measurement before and after breathing 21% O<sub>2</sub> and 50% O<sub>2</sub> (double-blinded).

Progress: Another 18 patients have been studied in a similar mananer as above to satisfy questions from the reviewers. The manuscript is still being reviewed by American Review of Respiratory Disease.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-12-91 Status: Ongoing

Title: The Effect of Magnesium on Ventricular Rate Control in Atrial Fibrillation.

Start date: 11 Dec 90	Estimated completion date:
Principal Investigator: Janet V. Hays, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): MAJ Maureen Arendt, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 15

Total number of subjects enrolled to date: 15

Periodic review date: Jun 93 Review results: See below

Objective(s): 1) To assess the immediate degree of rate control achieved with parenteral magnesium in patients with atrial fibrillation with a rapid ventricular response.

2) To assess the cumulative degree of rate control achieved at four hours with parenteral magnesium and digoxin in patients with atrial fibrillation with a rapid ventricular response.

Technical Approach: This study will examine the immediate effect of an intravenous bolus of magnesium sulfate on the ventricular response in patients with atrial fibrillation. It will also examine the combined effect of magnesium and digoxin on these same patients. It is expected that magnesium alone will cause an immediate decline in the ventricular rate compared to the placebo-controlled group and that the magnesium-digoxin combination will provide significantly greater rate control in four hours than may be achieved by digoxin alone. Patients will be drawn from those admitted to the Telemetry or Coronary Care Units with atrial fibrillation who meet the inclusion criteria.

Progress: 1) Patients still being collected-many have been screened, few enrolled. 2) study results submitted for publication in Annals of Emergency

C-12-91 (continued)

Medicine. Study results: 1)  $MgSO_4$  significantly decreases the ventricular rate control compared to placebo. 2)  $MgSO_4$  provides as good a rate control at five minutes than that obtained at 4 hours with digoxin. 3)  $MgSO_4$  plus digoxin shows a trend toward better control, though still not statistically significant.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-13-91 Status: Ongoing

Title: A Randomized, Double-Blind, Placebo Controlled Trial of the Effect of Lovastatin on the Incident of Primary Coronary Heart Disease in Patients with Mild to Moderate Elevations in Total and LDL-Cholesterol in Combination with Low HDL-Cholesterol.

Start date: 11 Dec 90	Estimated completion date: 1998
Principal Investigator: Joe M. Moody, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): Edwin J. Whitney, M.D., WHMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: as of 3 Dec 93  
 Total number of subjects enrolled to date: Over 5 thousand = 6,609  
 Periodic review date: \_\_\_\_\_ Review results: safety board review -> continue study

Objective(s): To investigate whether chronic treatment with lovastatin in patients without clinical evidence of coronary heart disease, slight to moderately elevated total and LDL cholesterol and low HDL-cholesterol will decrease the rate of fatal CHD of nonfatal myocardial infarction over a period of at least five years.

Technical Approach: Participants will be asked to maintain a standard low-fat and low-cholesterol diet throughout the study under the guidance of a dietician. Participants will be randomly assigned to either the placebo group or treatment group. The later group will receive 20 or 40 mg of lovastatin. Following initial evaluation at the Wilford Hall Wellness Clinic, they will be asked to return at six week intervals for the first eighteen months and then every six months thereafter. Lab tests will be performed at every follow-up visit.

Progress: As of 3 December 1993, over five thousand patients = 6,609 have been enrolled. Safety board review -> continue study.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-14-91                      Status: Ongoing

Title: Active Immunization of Early HIV Patients with Recombinant GP-160 HIV Protein: Phase II Study of Toxicity Immunotherapy, In Vivo Immunoregulation and Clinical Efficacy.

Start date: 8 Jan 91	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 47  
 Total number of subjects enrolled to date: 59  
 Periodic review date: 5 Nov 91                      Review results: \_\_\_\_\_

Objective(s): To conduct a Phase 2 trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, GP160 candidate vaccine, in patients with early HIV infection (Walter Reed Stage 1-2). Specific objectives include: 1) to continue to evaluate the immunogenicity and toxicity of this product; 2) to determine the parameters predictive of immuneresponsiveness; and 3) to determine the clinical efficacy of immunization with GP160 in the treatment of early HIV infection.

Technical Approach: As outlined in the study protocol.

Progress: Status of Study and Summary of Results to Date: 1) One case of moderate thrombocytopenia during this reporting period. No complications have resulted from this thrombocytopenia. As this protocol is placebo-controlled and double-blinded, it is not known whether this volunteer is on study vaccine or placebo. It should be noted that auto immune thrombocytopenia is not uncommon in HIV positive individuals. This volunteer continues to receive study vaccine. 2) One volunteer from the WHMC site committed suicide. This was not study related. 3) Several individuals have reached study endpoints:

C-14-91 (continued)

	<u>Secondary</u>	<u>Primary</u> <u>50% Decline</u> <u>in CD4 Ct.</u>	<u>Stage</u> <u>Progression</u>
WHMC	36	10	12
BAMC	6	1	1
WBAMC	6	1	1
DAH	10	1	1

4) There were no protocol revisions during this summary period.

Percent Completed: The study is still ongoing. 1) One hundred forty five volunteers signed consent forms and were enrolled in the study (BAMC-19; DAH-27; WBAMC-18; WHMC-81. 2) Sixteen volunteers failed to meet the pre-enrollment criteria or elected not to continue beyond the preevaluation period of study. 3) One hundred Twenty-nine volunteers have been randomized to receive study vaccine. However, subsequently 5 volunteers have been disenrolled (they no longer wish to participate) and we have lost contact with 3 others. No one has been disenrolled as a result of protocol violation. 4) Four volunteers, originally enrolled at the San Antonio site, are now being followed at Walter Reed Army Medical Center (as a result of convenience). 5) Summary of San Antonio site involvement.

<u>Site</u>	<u>#Enrolled</u>	<u>#Randomized</u>	<u>#Disenrolled</u>	<u>#Lost to Follow-up (not yet disenrolled)</u>
WHMC	81	75	1	2
BAMC	19	15	2	0
WBAMC	18	16	1	1
DAH	27	23	1	0

6) There have been 19 volunteers or their sponsors who have left active duty military service and continue to participate in the study under Secretary of the Army Designee status.

3. Specific problems: None.

4. Status of Resources: Adequate. There have been no gifts of equipment, supplies, money, or use of outside administrative received during the course of this study. Resources are supplied by the Jackson Foundation.

5. This study is ongoing. An interim look at the data will take place in December 1993 by a DSMB.

6. Estimated completion date: Not known; designed to be a 5-year study.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-16-91                      Status: Ongoing

Title: High Dose Cytosine Arabinose (HIDAC), Fractionated Total Body Irradiation (FTBI) and Autologous Bone Marrow Transplantation (BMT) to Treat Patients with Acute Lymphoblastic Leukemia (ALL) in Second Hematologic Remission: A Phase II Study.

Start date: 14 Jan 91	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the incidence of non-engraftment and of leukemic relapse in patients receiving autologous BMT (ABMT) following the ex vivo depletion of leukemic lymphoblasts from the autologous marrow using the immunogenetic purging technology.

Technical Approach: As outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-21-91                      Status: Ongoing

Title: Prospective Correlative Clinical Trial of Response to 5-FU in a Newly Developed Chemoresponse Assay Versus Clinical Response to Continuous 5-FU Infusion in Patients with Refractory Breast Cancer.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Howard A. Burris, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1 BAMC; 47 UTHSCSA  
 Periodic review date: thru 31 Dec 92                      Review results: \_\_\_\_\_

Objective(s): To conduct a prospective correlative clinical trial of the newly developed ChemoResponse Assay in patients with refractory breast cancer.

Technical Approach: As outlined in the study protocol.

Progress: The trial will remain open until enrollment is complete. No unexpected toxicities have been observed.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-28-91 Status: Ongoing

Title: Exercise Induced Oxyhemoglobin Desaturation as a Predictor of Nocturnal Desaturation in Chronic Obstructive Pulmonary Disease Patients.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Wayne T. Honeycutt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13

Total number of subjects enrolled to date: 33

Periodic review date: 19 Oct 92 Review results:

Objective(s): To determine whether exercise induced oxyhemoglobin desaturation in moderate to severe chronic obstructive pulmonary disease (COPD) patients can predict those who will have significant nocturnal desaturation.

Technical Approach: Approximately 40-50 subjects will be studied. Each patient will undergo an initial history and physical examination. Pulmonary function tests will be performed on the SensorMedics Horizon System to include pre- and post-bronchodilator forced vital capacity (FVC) and FEV1. Lung volumes and diffusion capacity for carbon monoxide will be measured. Resting arterial blood will be obtained in the supine position on room air. Desaturation with exercise will be evaluate during cardio-pulmonary testing using the Minolta Pulse-Oximeter. Nocturnal respiratory excursions, nasal airflow, ECG and oxyhemoglobin saturation will be monitored with an ambulatory system.

Progress: No further patients have been added. No manuscript has been prepared.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-34-91 Status: Ongoing

Title: Central Aortic Blood Pressure Variability During Cardiac Catheterization.

Start date: 28 Feb 91	Estimated completion date:
Principal Investigator: Bernard J. Rubal, Ph. D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5

Total number of subjects enrolled to date: 5

Periodic review date: Review results:

Objective(s): Retrospective study to evaluate the variability in central aortic systolic, diastolic and mean blood pressures to within  $\pm 1$  mm Hg in a consecutive series of 500 patients registered in the high-fidelity hemodynamic tape library at Brooke Army Medical Center.

Technical Approach: This is a retrospective study in which archived data is processed, A/D converted and computer analyzed.

Progress: A small number of patients have been entered to date due to limited access to clinical hemodynamic recording systems. Progress continues in computer analysis software for this project. A decision by medical maintenance to disconnect the physiologic recording system in the 3rd floor cath lab has temporarily made it impossible to review and digitize data from the archive library. This project will continue as soon as laboratory equipment is refurbished.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-37-91 Status: Terminated

Title: Hemodynamics of Cardiac Pacing Mode and Site of Electrical Activation on Myocardial Performance.

Start date: 6 Mar 91	Estimated completion date:
Principal Investigator: David M. Mego, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Cardiology	Associate Investigator(s): James Gilman, LTC, MC Leo Padove, MAJ, MC Bernard Rubal, Ph. D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date: Review results:

Objective(s): To compare the effects of right atrial, right ventricular, and atrioventricular sequential pacing on cardiac output while employing different right ventricular pacing sites.

Technical Approach: During cardiac catheterization, two temporary pacemaker will be placed into the heart. During each pacing mode, pacing will be performed above the patient's control sinus rate at rates of 70 to 89, 90 to 109 and 110 to 129. Paired comparisons will be made of the average cardiac output during right atrial pacing with the average cardiac output during the four other pacing modes.

Progress: Study terminated. This concept was validated in a published series of approximately 30 patients using similar methodology shortly after we began our study.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-38-91 Status: Terminated

Title: Effect of Sclerotherapy on Gastric Emptying.

Start date: 6 Mar 91	Estimated completion date:
Principal Investigator: Allan Parker, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Oyewole Toney, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 7

Periodic review date: 25 Sep 92 Review results:

Objective(s): To determine the effect, if any, of esophageal sclerotherapy on gastric emptying.

Technical Approach: Patients seen by the GI Service for sclerotherapy will be referred to nuclear medicine for gastric emptying study. The study will be performed in the standard manner.

Progress: Study terminated. We were unable to acquire sufficient patients to continue study.



Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-57-91 Status: Ongoing

Title: Spontaneous Bacterial Peritonitis Following Elective Esophageal Variceal Sclerotherapy: A Prospective Trial.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: John G. Carrougher, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: \_\_\_\_\_ Review results: No subjects

Objective(s): To evaluate the incident of spontaneous bacterial peritonitis (SBP) after elective esophageal variceal sclerotherapy (EVS).

Technical Approach: All patients with previous variceal bleeding who are receiving elective EVS and have ascites on physical examination will be eligible for the study. Patients will be admitted to the hospital and, following detailed history and physical exam, a paracentesis will be done. This will be sent for total cell count, polymorphonuclear count, total protein and albumin, cytology, aerobic and anaerobic cultures, and gram stain. The diagnosis of SBP will be made if the PMN count is 250/mm<sup>3</sup> or greater and/or positive ascitic fluid cultures.

Progress: No subjects have been enrolled. Study is to remain ongoing for one more year.

### Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-61-91 Status: Completed

Title: Effects of Large Volume Paracentesis on Pulmonary Functions Tests

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Carlos Angueira, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: 15 patients total  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effects of large volume paracentesis on pulmonary functions in patients with ascites.

Technical Approach: The patient population will consist of inpatients who are admitted because of ascites causing abdominal discomfort or respiratory symptoms. Large volume paracentesis (LVP) is indicated in these patients as part of their treatment program. Pulmonary function tests (PFTs) will be performed prior to the LVP. These will include all lung flows and lung volumes. Arterial blood gases will be performed prior to and after PFTs. Ascitic fluid will be sent for cell count, chemistries and cytology.

Progress: Study completed. Data is being analyzed. Manuscript is in preparation for submission for publication.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-62-91                      Status: Ongoing

Title: Treatment of Refractory Ulcers in Epidermolysis Bullosa Using Cultured Epidermal Allografts.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Wallace B. Smith, CPT. MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Dermatology	Associate Investigator(s): Jerome C. Hill, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To successfully harvest and culture epidermal kartinocytes from the parent of a child with epidermolysis bullosa and develop a multilayer epidermal allograft to be used to cover nonhealing erosions.

Technical Approach: Epidermal allografts from cells obtained from a skin biopsy performed on the parent of a child with junctional epidermolysis bullosa will be isolated and grown. The cells thus obtained will be planted on plastic tissue culture plates containing Kartinocyte Growth Medium which has been developed for the growth of kartinocytes. We will attempt manipulations of the media to induce the growth of multilayer epidermal sheets which will be transplanted into nonhealing eroded areas on the child with junctional epidermolysis bullosa.

Progress: No report provided by principal investigator.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-65-91                      Status: Ongoing

Title: Phase I Trial of Tetraplatin Administered for Five Consecutive Days Every 28 Days.

Start date: 24 Jul 91	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the maximum tolerated dose of Tetraplatin administered on a daily x 5 every 28 days schedule.

2) To determine the qualitative and quantitative toxicities of Tetraplatin on this schedule.

3) To determine the recommended dose for Tetraplatin on this schedule in Phase II trials.

Technical Approach: This is a phase I study of tetraplatin administered on a daily x 5 schedule. Dose levels are 1, 2, 3.3, 5, 7, 9, and 11 mg/m<sup>2</sup>.

Progress: A total of 35 patients were enrolled. The dose limiting toxicity was peripheral neuropathy seen in all five patients who received cumulative doses in excess of 150 mg/m<sup>2</sup>. Because of the severity of this toxicity, phase II was not recommended. Seven of the thirty five patients were enrolled at BAMC. There are currently none remaining on study.

Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-68-91 Status: Ongoing

Title: High Dose Cyclophosphamide, Etoposide, and Carmustine with DTIC and Autologous Marrow Rescue for Myeloma and Relapsed or Refractory Lymphoma, A Phase I-II Study.

Start date: 30 Jul 91	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): W. Jeffrey Baker, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine the complete response rate and survival of patients with relapsed or refractory Hodgkin's and non-Hodgkin's lymphoma treated with maximum tolerated dose of DTIC in combination with high dose cyclophosphamide, etoposide, and carmustine with autologous bone marrow rescue.

2) To determine the complete response rate and survival of patients with multiple myeloma treated with the maximum tolerated dose of DTIC in combination with high dose cyclophosphamide, etoposide, and carmustine with autologous bone marrow rescue.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains ongoing for eligible patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-71-91 Status: Ongoing

Title: The Polymerase Chain Reaction in the Diagnosis of Histoplasmosis.

Start date: 30 Aug 91	Estimated completion date: Dec 93
Principal Investigator: John H. Schrank, Jr, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): Victor V. Tyron, Ph. D. C. Kenneth McAllister, Jr., COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To apply the polymerase chain reaction (PCR) in the detection and rapid diagnosis of histoplasmosis.

Technical Approach and Progress: The project consists of two experimental Phases:

a. Sequencing of amplified DNA to identify *H. capsulatum*-specific 18S ribosomal gene sequences. At present, we have sequenced the entire 1700bp gene from the G186AS *H. capsulatum* strain. A unique extra 400 base pair area was identified which seems to be contained by only this strain. We are currently attempting to sequence other strains to see if they also contain this extra 400bp piece.

b. Amplification of *H. capsulatum* DNA using organism-specific primers from organism in culture. We have chosen several unique primers from the sequenced gene and are testing them and modifying the actual amplification process in an attempt to increase the sensitivity and specificity of the assay.

Progress: We have successfully amplified, cloned, and sequenced the entire 18s ribosomal gene from the G186AS strain of histoplasmosis capsulatum.  
Analysis

C-71-91 (continued)

of the sequence (see Figure 1) revealed close homology with several other *Blastomyces dermatitidis*. In addition, we have also obtained samples of DNA for five other strains of *histoplasma capsulatum*. Preliminary results from amplification of these strains have revealed that the size of their 18s ribosomal gene is shorter than the already sequenced G186AS gene by about 400 base pairs.

# **Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** C-72-91      **Status:** Terminated

**Title:** Total Bowel Transit Time During Resting, Training, and Exercise Periods in Competitive Runners.

<b>Start date:</b> 30 Aug 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Michael Cassaday, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department Medicine/Gastroenterology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the transit of an unabsorbable marker such as charcoal in competitive runners.

**Technical Approach:** Approximately 40-50 runners will be studied. They will be asked to ingest 2 ounces of activated charcoal (Inst Char) suspension in three different sessions while remaining on their usual diets, but the intensity of the training varied. Session one will be during a period of routine training; session two will be the day of the race; and session three will be after a 72 hour rest period.

**Progress:** As of 1 Dec 93, no patients have been entered in this study and therefore there is no reportable data. Of note, principal investigator has been assigned to Frankfurt, Germany and therefore protocol should be terminated.



# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-83-91 Status: Completed

Title: A Comparison of Exercise Tc-99m Sestamibi Myocardial Scintigraphy and Adenosine Tc-99m Sestamibi Myocardial Scintigraphy for Diagnosis of Coronary Artery Disease in Patients with Left Bundle Branch Block.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): James Heironimus, LTC, USAF, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11

Total number of subjects enrolled to date: 11

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the comparative utility of two non-invasive testing protocols in diagnosing coronary artery disease in patients with left bundle branch block.

Technical Approach: Patients will undergo an outpatient Tc-99m sestamibi exercise treadmill test via routine exercise protocols. After appropriate time interval for decay of the previously administered isotope, the patients will undergo an intravenous infusion of 140 ug/kg/min for 6 minutes. Both tests will involve the injection of 25 mCi Tc-99m sestamibi after stress and at rest with SPECT imaging. Patients will then undergo heart catheterization which will be performed using standard techniques to include selective coronary angiography and left ventriculography.

Progress: Study completed. Results published in American Journal of Cardiology, Jan 93.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-85-91 Status: Ongoing

Title: Open Label Dose-Tolerance Study of Intravenous Ilmofofosine Administered by a 120 Hour Continuous Infusion Every 21 Days to Patients with Cancer Refractory to Standard Treatment.

Start date: 30 Sep 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2 BAMC; 23 UTHSCSA  
 Periodic review date: thru 31 Dec 92 Review results:

Objective(s): To determine the maximum tolerated dose of ilmofofosine when administered intravenously as a 120-hour continuous infusion every 21 days and to describe the toxicity of ilmofofosine when administered on the schedule described above.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No increase in cose achieved with prolongation of the infusion duration. Phase II trials are being pursued with 120 hour infusion at 300 g/m2/day.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-88-91 Status: Terminated

Title: An Open Multicenter Randomized, Dose-Ranging Study Azithromycin in the Treatment of Disseminated Mycobacterium Avium-Intracellular Complex Infection (MAC) in Patients with Acquired Immune Deficiency Syndrome (AIDS).

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: James W. Martin, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To evaluate the efficacy and safety of two doses of azithromycin given chronically for the treat of M. avium bacteremia in AIDS pateints.

TECHNICAL APPROACH: Therapy will follow the outline in the study protocol.

PROGRESS: This study was terminated with no patients entered due to withdrawal of the study by MMCAR-the sponsoring agency. We entered no patients at BAMC and received no study drug.

Detail Summary Sheet

Date: 14 Dec 93 Protocol Number: C-94-91 Status: Ongoing

Title: Evaluation of the Effect of Forceps Size on the Adequacy Specimens Obtained by Transbronchial Biopsy.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC H.M. Blanton, MAJ, MC
Key words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: 19 Oct 92 Review results: \_\_\_\_\_

Objective(s): To determine the relative diagnostic yield of bronchoscopic biopsy performed with either small or large smooth edged forceps.

Technical Approach: Each patient will have 3 biopsies done with the large and 3 biopsies done with the small forceps in randomized order. If more tissue is needed based on visual inspection of the material, one or more additional biopsies will be taken with each forceps. Biopsies taken with each of the two forceps will be submitted to pathology for examination. The pathologist will be blinded as to which forceps was used for each biopsy.

Progress: About 30 patients were studied with a finding of significantly more tissue obtained with the large forcep. This manuscript was published in the most recent issue of the American Review of Respiratory disease.

We will continue the study to include about 30-35 total patients.

**Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-92-5                      **Status:** Ongoing

**Title:** Pharmacodynamic Doppler Determination of Mitral Valve Area in Patients with Significant Aortic Insufficiency

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ David M. Mego, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Cardiology	<b>Associate Investigator(s):</b> LTC Joseph P. Johns, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b> 0	<b>Estimated cumulative OMA cost:</b> 0

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 2  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To assess the hemodynamic effects of amyl nitrite in patients with combined mitral stenosis and aortic regurgitation, and to assess the accuracy of Doppler-determined mitral valve areas during these effects.

**Technical Approach:** Study will involve five patients with combined mitral stenosis and aortic insufficiency who are undergoing diagnostic cardiac catheterization.

**Progress:** This lab is now completed and we will resume enrollment of patients as they are identified.

**Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-92-11                      **Status:** Ongoing

**Title:** Household Transmission of Hepatitis C Virus in Military Populations

<b>Start date:</b> Jan 92	<b>Estimated completion date:</b> Dec 95
<b>Principal Investigator:</b> LTC Shailesh Kadakia, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Gastroenterology	<b>Associate Investigator(s):</b> MAJ Thomas Kepczyk, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 12 - consisting of  
**Total number of subjects enrolled to date:** patients and 9 household  
**Periodic review date:** \_\_\_\_\_ **Review results:** contacts

**Objective(s):** Study will consist of enrolling anti-HCV-positive individuals and anti-HCV-negative individuals with a diagnosis of chronic NANB hepatitis and their household contacts.

**Technical Approach:** Three (3) index cases tested positive for anti-HCV. The serum samples were submitted for further testing to include anti-HCV by ELISA, as well as by RIBA and finally by PCR to detect HCV-RNA. These samples were obtained from 3 index cases and 9 additional household contacts. Total of 56 index patients from BAMC, FAMC, WRAMC, and TAMC have been included in the study with 84 household contacts.

**Progress:** As of 1 December 93, no new patients have been added. Study is ongoing.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-13                      Status: Ongoing

Title: Use of APACHE II Score to Predict Length of Mechanical Ventilation in Medical Intensive Care Patients

Start date:	Estimated completion date:
Principal Investigator: CPT James M. Brassard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): LTC James E. Johnson, MC LTC Greg Anders, MC LTC Herman M. Blanton, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 79  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine in a prospective fashion the correlation of first day APACHE II scores in patients admitted to an intensive care unit for acute respiratory failure secondary to ARDS, COPD. Pneumonia or Cardiogenic Pulmonary Edema with eventual duration of requirement for mechanical ventilation.

Technical Approach: APACHE (Acute Physiology, Age, Chronic Health Evaluation) Scores were derived from data obtained within 24 hours of ICU admission for patients admitted with the diagnosis of nonoperative respiratory disease. Mean scores were determined for 3 groups. 1-not intubated, 2- mechanical ventilator <14 days; 3-mechanical ventilator >14 days.

Progress: No further patients have been entered in this study.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-14

Status: Ongoing

Title: Cell Culture Model to Test the Relative Independence of Cancer Cells to Reduced T3 Levels by Comparison to More Normal Cells

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Isidoro Chapa
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if reversible hypothyroidism can be induced briefly in euthyroid patients, conceivably normal cells can be induced into a hypometabolic state while the diseased cells continue at their baseline or near baseline metabolic level.

Technical Approach: Cell cultures will be grown from prostate tissue recently removed with TURP by urology and documented prostate cancer present by pathological exam.

Progress: The data has been written up and submitted for publication which is pending at this time.



Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-92-16 Status: Completed

Title: Incidence and Distribution of Gastrointestinal Lesions in Patients with Iron Deficiency Anemia

Start date: Sep 91	Estimated completion date: 12 Jun 93
Principal Investigator: MAJ Thomas Kepczyk, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): LTC Shailesh Kadakia, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 59  
Total number of subjects enrolled to date: 59  
Periodic review date: 12 Mar 93 Review results:

Objective(s): To evaluate the incidence and distribution of gastrointestinal (GI) lesions in patients with documented iron deficiency anemia by performing both upper and lower gastrointestinal endoscopy (EGD/colonoscopy), small bowel biopsy and enterolysis in patients without lesions at EGD and colonoscopy.

Technical Approach: One-hundred (100) patients over the age of 45, who present to the GI Clinic for evaluation of iron deficiency anemia of unknown etiology will be entered into the study.

Progress: As of 1 Dec 93, data has now been collected a manuscript is being prepared for the purpose of publication. We are not anticipating collection of any more data for this protocol. Of note, principal investigator, Dr. Kepczyk has PCS'd to Fitzsimons AMC. However, the manuscript is being prepared in conjunction with Dr. Kepczyk and Dr. Kadakia for the purpose of publication.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-18 Status: Ongoing

Title: The Natural History of HIV Infection and Disease in United States Military Beneficiaries

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 131  
 Total number of subjects enrolled to date: 131  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): a) To systematically document the natural disease progression in individuals with HIV infections in a general military population. b) To form a study cohort which will be eligible for participation in treatment protocols and for other studies related to specific aspects of the descriptive elements (natural history) of HIV infection.

Technical Approach: Proposal is to organize information in a data base now being routinely collected on HIV patients into a data base, henceforth referred to as the BAMC Natural History Study, in such a way that more scientifically valid information will be forthcoming and safeguards to patient confidentiality are met.

Progress: 184 BAMC patients have been enrolled to date. This protocol is a component of an overall Tri-service natural history study which now has a registry of over 1800 patients.

# Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: C-92-23

Status: Ongoing

Title: An Open-Label Multi-Investigator Comparative Study of the Safety and Efficacy of Cefipime and Ceftazidime in the Treatment of Hospitalized Patients with Septicemia

Start date:	Estimated completion date:
Principal Investigator: MAJ John H. Schrank, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): COL C. Kenneth McAllister, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 30  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy of cefepime (2 g q8h) versus ceftazidime (2 g q8h) in the treatment of patients with clinically and bacteriologically documented bacterial septicemia with or without a confirmed site of local infection. Emphasis is placed on the isolation of pathogen(s) from 2 or more sets of pretreatment blood cultures from patients with suspected septicemia. An additional objective is to achieve further experience concerning the safety and tolerance of cefepime compared to ceftazidime, with both agents administered as a 6-g total daily dose in patients with serious, life-threatening septicemia.

Technical Approach: This is an open-label, randomized, comparative, multi-center evaluation of the safety and efficacy of cefepime versus ceftazidime in the treatment of clinically and bacteriologically documented septicemia, with or without a confirmed site of local infection. Patients who meet the inclusion and pass the exclusion criteria will be randomly assigned to receive either cefepime or ceftazidime (1:1 randomization, cefepime:ceftazidime). It is anticipated that approximately 1000 patients (100 evaluable per treatment group) will be enrolled at 30 to 40 selected sites over a period approximately

C-92-23 (continued)

12 months.

Progress: As of this date, 30 patients have been enrolled in study. Of those

30, 2 patients did not receive any study drug. One patient was disqualified because he had received more than 24 hours of prestudy antibiotics and one patient had a blood culture which grew *Pseudomonas aeruginosa* and was clinically felt to require aminoglycoside therapy. Remaining 28 patients met both inclusion and exclusion criteria and were randomized to receive either Ceftazidime or Cefepime. As of 20 January 1994, the study will be terminated as requested by Bristol-Myers Squibb Pharmaceutical Research Institute. All remaining study drug will be returned to company and no further patients will be enrolled from this date.

### Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: C-92-25

Status: Ongoing

Title: Randomized, Double-Blind Study Comparing Medroxyprogesterone Acetate and Placebo in Cancer Cachexia

Start date: Apr 92	Estimated completion date: Dec 94
Principal Investigator: CPT Karen J. Bowen, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): LTC Timothy J. O'Rourke, MC
Key Words: Cachexia, Medroxy- progesterone, Cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 10  
Periodic review date: 31 Dec 93 Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the effect of medroxyprogesterone acetate (MPA) vs. placebo in patients with cancer and weight loss. 2) A secondary goal is to evaluate the quality of life in patients receiving MPA.

Technical Approach: Ninety (90) patients, 18 years of age and older, with unresectable or recurrent solid tumors will be randomized to one of two arms matching patients by performance status, ongoing chemotherapy, and tumor type. Eligible patients will be placed on one arm of the study to receive either MPA or placebo. Patients receiving MP will be treated with a dose of 400 mg given orally once daily. Treatment will continue indefinitely unless patients are removed from the study at the discretion of the treating physician.

Progress: A total of 11 patients have now been enrolled. No problems with the protocol design. As the study is blinded, no results are yet available.

# Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-30

Status: Ongoing

Title: Regression of Metaplastic Esophageal Epithelium With Omeprazole

Start date: Feb 92	Estimated completion date: Jan 95
Principal Investigator: MAJ Richard Shaffer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): LTC Shailesh Kadakia, MC MAJ John G. Carrougher, MC
Key Words:	
Cumulative MEDCASE cost: \$1000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 21  
 Total number of subjects enrolled to date: 6  
 Periodic review date: Mar 93 Review results: \_\_\_\_\_

Objective(s): To determine if regression of metaplastic esophageal epithelium (Barrett's esophagus) can be induced by utilizing a hydrogen proton pump inhibitor (Omeprazole) to create an achlorhydric environment.

Technical Approach: 80 patients will be enrolled. Age, sex, duration of disease and prior therapy will be noted for demographic data. Primary exclusion criteria will be due to an indeterminant gastro-esophageal junction by direct endoscopic observation. After complete information outlining the requirements for the study, the current FDA status of Omeprazole and other literature regarding long-term usage of Omeprazole, those subjects declining enrollment in the Omeprazole study group will serve as controls (as they are routinely undergoing annual surveillance). Those meeting endoscopic criteria will be randomized to omeprazole or H<sub>2</sub>-blockers.

Progress: Twenty-one patients enrolled with 15 of 21 patients at the 1 1/2 year point of the study, and the remainder at 9 months of the study. To date, no change in Barrett's epithelium from baseline measurements or from reference tattoo noted at 3, 9, and 15 months. No complications due to study. A separate analysis was performed on the agilitivity of India ink tatooing in the esophagus and this was presented at the Army ACP meeting November 1993, in Orlando, Florida. Project continuation of the study for an additional 1 year.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-34                      Status: Ongoing

Title: Phase I Trial of RP60475 Administered as a One-Half Hour Infusion Every 21 Days

Start date: 29 Jan 92	Estimated completion date: 15 May 93
Principal Investigator: MAJ Howard A. Burris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date: 9  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the maximum tolerated dose of RP60475 administered as a 1/2 hour infusion given every 21 days. 2) To determine the qualitative and quantitative toxicities of RP60475 on this schedule. 3) To determine the recommended dose for RP60475 on this schedule in Phase II trials. 4) To characterize the pharmacokinetics/pharmacodynamics of RP60475. 5) To collect information about antitumor effects of RP60475.

Technical Approach: This is a rising dose, open-label, Phase I study of RP 60475 utilizing a dosage regimen of a 1/2 hour intravenous infusion every 3 weeks. Standard methodology for a Phase I oncology study will be utilized. The dosage levels to be studied are 12, 24, 40, 60, 84, 110, 130, 156, and 180 mg/m<sup>2</sup>.

Progress: Nine patients were enrolled on this protocol at BAMC. Accrual goals were met and the study will close on 15 May 93. Dose limiting toxicities were myelosuppression. Phase II trials are being planned.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-38                      Status: Completed

Title: Pharmacokinetic Guided Phase I Evaluation of 7U85 Mesylate  
Administered Intravenously as a Two-Hour Infusion Every 28 Days

Start date:	Estimated completion date:
Principal Investigator: MAJ Howard A. Burris II, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the maximum tolerated dose (MTD) of 7U85 mesylate when administered intravenously, as a two-hour infusion once every 28 days. 2) To define qualitatively and quantitatively the toxicities of 7U85 mesylate when administered as a single dose every 28 days. 3) To apply a pharmacokinetic guided dose escalation procedure, in which AUC is measured, in order to decrease numbers of patients to achieve the MTD. 4) To determine the basic pharmacokinetics of 7U85 mesylate by study of plasma and urinary concentrations of the agent in patients. 5) To collect information about the antitumor effects of 7U85 mesylate.

Technical Approach: This is a rising dose, open-label Phase I study of 7U85 administered as a two hour infusion every 21-28 days. Standard methodology for a Phase I oncology study will be utilized. This protocol was amended and revised to decrease the study dose of drug and to allow a more conservative dose escalation scale. G-CSF was added to the regimen to prevent prolonged neutropenia.

Progress: Difficulties with hepatotoxicity are limiting further development of RP60475 - observed on retreatment at the normally tolerated dose.



### Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-41

Status: Ongoing

Title: Quantification of T3 Receptors in Human Cancer Tissue Compared to the Tissue from the Clear Margin of the Same Surgical Specimen

Start date:	Estimated completion date:
Principal Investigator: Kevin Carlin, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Patients whose medical care has already dictated a surgical procedure for diagnosis and/or therapy of a possible cancer will be considered as a possible candidate to enter the study. There will be no exclusion factors. The only impact to patients for participation is the tissue that was to be removed any will undergo additional analysis.

Technical Approach: Patients with known or strongly suspected cancers who are undergoing surgery for diagnosis and/or therapy will have postop examination and testing of a representative sample of their mass and the clear margin. Samples will have their T3 receptors quantified by a previously utilized, well documented method. If the hypothesis is correct, there should be a higher percentage of T3 receptors in the clear margin than in the cancer cells.

Progress: The laboratory is having difficulty getting the T<sub>3</sub> assay to work.

**Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-92-53                      **Status:** Ongoing

**Title:** Core Protocol for HIV Developmental Diagnostic (Adult).

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ J. William Kelly, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Infectious Disease	<b>Associate Investigator(s):</b> Donald S. Burke, COL, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 90  
**Total number of subjects enrolled to date:** 90  
**Periodic review date:** 22 Mar 93                      **Review results:** \_\_\_\_\_

**Objective(s):** a) To develop and evaluate new and/or improved laboratory methods for establishing the diagnosis of HIV, and to correlate detectable HIV virus, HIV antigen, and/or HIV nucleic acid in blood with clinical status. b) To develop and evaluate new and/or improved laboratory methods for assessing the virus-specific immune response to HIV infection, and to correlate detection of virus-specific antibody or cell mediated immune responses with clinical status.

**Technical Approach:** Under this protocol, the patient will be asked to give informed consent that his/her blood can be used for the general purpose of development and evaluation of virologic and immunologic techniques, and that his/her clinical records can be reviewed in order to correlate test results with his/her clinical condition. Solicitation of patients will be done in the Infectious Disease Clinic by a protocol manager on the Infectious Disease Clinic.

**Progress:** Approximately 146 subjects have been enrolled to date. Serum and cells from these patients have been banked for use in development of diagnostic methods.

**Detail Summary Sheet**

**Date:** 15 Dec 93

**Protocol Number:** C-92-54

**Status:** Completed

**Title:** A Topical Barrier Substance for Allergic and Irritant Contact Dermatitis

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> CPT W. Bret Smith, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Dermatology	<b>Associate Investigator(s):</b> CPT Mark Bonner, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 10  
**Total number of subjects enrolled to date:** 10  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** Will a new topical skin barrier substance (trade name-Dermashield, Benchmark Lab) provide protection against allergic contact dermatitis from poison ivy resin and/or protect the skin from an irritant dermatitis? A random age group (18-60 years) of 10 people believed to have an allergic contact dermatitis to poison ivy will be studied using their forearms as a bilateral comparison (one arm with, and one without Dermashield applied prior to application of poison ivy resin and sodium lauryl sulfate).

**Technical Approach:** A random healthy population of 10 men and women aged 18-60 years believed to have an allergic contact dermatitis to poison ivy will be chosen. Each person will serve as their own control using one forearm to compare to the other.

**Progress:** The study was completed and the dermashield was found to not be effective protection. The results were submitted for publication in the Archives of Dermatology.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-58 Status: Terminated

Title: Ketoconazole Absorption in HIV Infected Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ Joseph Morris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): MAJ J. William Kelly, MC M. Patricia Joyce, MD C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25  
Total number of subjects enrolled to date: 25

Periodic review date: Review results:

Objective(s): To determine if ketoconazole absorption is abnormal in patients with HIV infection.

Technical Approach: Approximately 20-30 subjects will be required, consisting of 10-15 healthy individuals as controls and 10-15 patients with HIV infection. Subjects will be drawn from the patients followed at the BAMC Infectious Disease Clinic. Subjects, as well as their medical records, will be reviewed to exclude the possibility of an opportunistic infection requiring prompt treatment. The controls will be healthy age and sex matched volunteers. Patients already on ketoconazole, terfenadine, H<sub>2</sub> blockers, and/or antacids will have the drugs discontinued 3 days prior to the study. After informed consent is obtained, a tablet of ketoconazole (200mg) with 200 ml. of water will be given to each participant. Venous blood samples will be drawn at 0.1, and 2 hours after the ingestion of the ketoconazole tablet.

Progress: 25 subjects (11 HIV patients with early stage disease, 9 HIV patients with late stage disease, and 5 uninfected controls) have been enrolled. Although there was a small trend in the ketoconazole absorption with increasing stage of HIV disease, it was not statistically significant. In addition, the values in all groups were within the accepted range of normal. Results were presented at the 33rd Interscience Conference on Antimicrobial Agents and Chemotherapy.

# **Detail Summary Sheet**

**Date:** 31 Dec 93                      **Protocol Number:** C-92-64                      **Status:** Ongoing

**Title:** A Phase I Trial of OKT3 (Anti-CD3) Monoclonal Antibody After High Dose Chemotherapy and Autologous Bone Marrow Transplantation in Patients with Breast Cancer.

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Svetislava J. Vukelja, MAJ, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b> W. Jeff Baker, MAJ, MC Barbara Reeb, DAC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the toxicities as well as the maximum tolerated dose of OKT3 antibody given after high-dose chemotherapy and autologous bone marrow transplantation in patients with breast cancer. 2) To determine the effect of OKT3 antibody on lymphocyte reconstitution postgrafting compared to lymphocyte reconstitution that occurs without administration of OKT3 after tandem high-dose chemotherapy and autologous bone marrow transplantation in patients with breast cancer. 3) If tumors are easily assessible for biopsy, determination at the results of cytotoxicity assays on tumor cells using OKT3 stimulated as well as unstimulated peripheral blood lymphocytes from the patients.

**Technical Approach:** Study has not started. We do not have HSC approval.

# Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: C-92-65

Status: Ongoing

Title: A Phase I Trial Of Toremifene and Doxorubicin in Patients with Advanced Malignancies

Start date: 13 Apr 92	Estimated completion date: 1 Jan 94
Principal Investigator: Howard A. Burris III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11

Total number of subjects enrolled to date: 11

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the maximally protective dose (i.e., that dose associated with clinically acceptable, predictable, and reversible toxicity) of toremifene when administered concomitantly. 2) To determine plasma pharmacokinetics of toremifene and doxorubicin when administered concomitantly. 3) To determine the chemosensitizing activity of toremifene when administered with doxorubicin. 4) To assay tissue samples for toremifene concentrations, and expression of MDR (multi-drug resistance) and associated gene-products pre- and post-toremifene treatment. 5) To evaluate for clinical evidence of MDR reversal by restoration of chemotherapeutic responsiveness in doxorubicin refractory cancer patient. 6) To determine the recommended dose for toremifene when given with doxorubicin (60 mg/m<sup>2</sup>IV every 21 days) for Phase II trials.

Technical Approach: Patients with advanced or refractory solid tumors will be treated at each dose level of toremifene. Two patients will have been previously treated with doxorubicin, and two patients will not have been previously treated with doxorubicin. One patient from each of these 2 groups (prior or no prior doxorubicin) must be followed for 3 weeks with the second patient followed for a minimum of one week prior to proceeding to the next dose level.

C-92-65 (continued)

Progress: Eleven patients have been enrolled on this protocol at BAMC. Accrual is ongoing, and the current dose level of toremifene is 600 mg. As expected, myelosuppression has been significant.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-68 Status: Ongoing

Title: Prophylactic Low Dose Coumadin and Antiplatelet Therapy in the Nephrotic Syndrome Secondary to Membranous Nephropathy.

Start date: Jul 92	Estimated completion date: Jun 97
Principal Investigator: Gail L. Seiken, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s):
Key Words: Nephrotic Syndrome Membranous nephropathy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Jan 93 Review results: N/A

Objective(s): 1) To prospectively examine the incidence of thrombotic events in patients with nephrotic syndrome secondary to membranous nephropathy. 2) To prospectively evaluate the role of low dose coumadin and antiplatelet therapy in the prevention of thrombotic complication of nephrotic syndrome secondary to membranous nephropathy. 3) To prospectively evaluate the benefit of anticoagulation in patients with documented thrombosis associated with the nephrotic syndrome of membranous nephropathy.

Technical Approach: This is a prospective, randomized study designed to evaluate the incidence of thromboembolic complications in patients with idiopathic membranous glomerulopathy, and the potential role for prophylactic low dose coumadin and antiplatelet therapy in the prevention of these complications.

Progress: No patients have been entered into study thus far. All information is current. Study remains ongoing for patient accrual.



Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-92-69 Status: Ongoing

Title: A Double-Blind, Randomized, Comparative, Multicenter Study of CI-983 in the Treatment of Community-Acquired Bacterial Pneumonia

Start date:	Estimated completion date:
Principal Investigator: MAJ Gregg T. Anders, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): CPT Dan Loube, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To evaluate the efficacy and safety of two dosage regimens of CI-983 versus cefaclor in the treatment of patients with community-acquired bacterial pneumonia.

Technical Approach: Double-blind trial comparing one antibiotic to another in community-acquired pneumonia.

Progress: No change in current status. No patients enrolled to date.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-70                      Status: Ongoing

Title: The Prevalence of Colonic Neoplasms in Patients with Known Breast Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ John Carrougher, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): CPT Karen Bowen, MC LTC Shailesh Kadakia, MC CPT Richard Shaffer, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 38  
 Periodic review date: 15 Oct 92      Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine the prevalence of colonic neoplasms in female patients with breast adenocarcinoma. We wish to determine if colonic neoplasms occur in greater frequency in patients with breast carcinoma than in a similarly matched control population. The information obtained from this study should be used to establish guidelines on colonoscopic surveillance in patients with breast cancer.

Technical Approach: Patient population will consist of all patients currently receiving care for breast adenocarcinoma in the oncology clinic at Brooke Army Medical Center. A letter will be sent to each patient soliciting participation. All participants will undergo colon screening to be accomplished by colonoscopy.

Progress: Study remains ongoing for patient followup.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-73                      Status: Completed

Title: Immunoglobulin and Lymphocyte Responses in Systemic Lupus Erythematosus Patients Following Immunization with Three Clinically Relevant Vaccines

Start date: Aug 92	Estimated completion date: Aug 93
Principal Investigator: MAJ Steven A. Older, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Rheumatology	Associate Investigator(s): MAJ Nicholas J. Battafarano, MC
Key Words: SLE Immunization	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 21  
 Total number of subjects enrolled to date: 21  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine how SLE patients respond to immunization. 2) To determine if there is any difference between the multiple variables associated with the SLE patients who demonstrate an adequate response and those who demonstrate an inadequate response. 3) To identify clinically useful applications to immunization prescription in SLE patients. 4) To identify characteristics of the immunologic response that provide insight into the underlying pathophysiology.

Technical Approach: Approximately twenty SLE patients from the Rheumatology Clinic will be entered into the study. Evaluation and phlebotomy will be performed in the Rheumatology Clinic at Beach Pavilion.

Progress: The BAMC limb of this study is completed. Final results expected from FAMC in 3-6 months.

# **Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** C-92-81      **Status:** Ongoing

**Title:** The Induction of the Alpha-Delta Sleep Anomaly and Fibromyalgia Symptoms in Athletes vs. Sedentary Controls; Correlations with Somatomedin-C

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Steven A. Older, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Rheumatology	<b>Associate Investigator(s):</b> MAJ Max Duncan, MC John Ward, Ph.D. I. Jon Russell, M.D., Ph.D.
<b>Key Words:</b> Expensive Time consuming Tedious	
<b>Cumulative MEDCASE cost:</b> None	<b>Estimated cumulative OMA cost:</b> None

**Number of subjects enrolled during reporting period:** 6  
**Total number of subjects enrolled to date:** 6  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** Two questions will be posed: a) does prior physical conditioning protect against the development of fibromyalgia symptoms in sleep-deprived individuals, and b) does Somatomedin-C, a growth factor associated with both sleep and tissue healing, play a role in the pathophysiology of fibromyalgia?

**Technical Approach:** Thirty-two active duty military volunteers between the ages of 18 and 40 will be studied in two groups. Sixteen highly conditioned athletes (8 females and 8 males) will constitute the study group ("athlete group"). An Equal number of healthy but sedentary individuals, age and sex mated, will serve as the control group ("sedentary group").

**Progress:** Several problems were presented during the pilot phase of this protocol. Technology and technologists of the contracted sleep study group were inadequate. Appropriate Delta wave interruption was not possible despite numerous discussions and corrections. It was concluded from a clinical standpoint that no additional information was gained by the performance of dolorimetry testing both pre- and post-sleep. The sleep study phase of the project will be held off campus at a sleep disorder center.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-83                      Status: Ongoing

Title: A Randomized Phase II/III Study of PIXY321 (GM-CSF/IL-3 S. cerevisiae Fusion Protein) or Placebo in Combination with DHAP as Salvage Therapy for Lymphoma

Start date: 28 Aug 92	Estimated completion date: 1 Jan 94
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Principal Investigator: CPT Howard A. Burris III, MC	Facility: Brooke Army Medical Center, Texas
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Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): CPT Karen J. Bowen, MC
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Key Words:

Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
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Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the effectiveness of SC PIXY321 to placebo in reducing the severity of chemotherapy-associated myelosuppression in patients with relapsed or refractory lymphoma treated with DHAP chemotherapy.

Technical Approach: This will be a multi-center, randomized, double blind, phase II/III study in which eligible patients will be randomized to received either 2 cycles of DHAP chemotherapy followed by a fixed dose of SC PIXY321 or 2 cycles DHAP chemotherapy followed by placebo.

Progress: Five patients have been enrolled on this protocol at BAMC. Accrual is ongoing. Data from the randomized portion of the trial has not been evaluated.

### Detail Summary Sheet

Date: 15 Dec 93  
Ongoing

Protocol Number: C-92-85

Status:

Title: Possible Hormone Manipulations in The Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To culture human T cells in a culture medium devoid of human or calf serum. This will allow full knowledge of what actually is necessary to culture T cells.

Technical Approach: Volunteers between ages 18-65 who are not pregnant will donate 10 ml of blood after signing a consent form. This 10 ml of blood will then undergo a process in order to culture normal human T cells. The 10 ml of whole blood will then be spun down to separate red blood cells from white blood cells. The buffy coat containing the white blood cells will then be removed and mononuclear leukocytes obtained via Ficoll-hypaque isopyphic centrifugation.

Progress: This study has shown HIV is independent of thyroid hormone. This data has been accepted in an abstract/poster to First National Conference Human Petrovime (NIH, CDC) Dec 93, Washington, DC.

We are now repeating this experiment in larger groups with results to be published if once again, T cells are found to be independent. There are no complications/misadventures with all blood drawn only on subjects who also are part of the project.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-88 Status: Ongoing

Title: Validation of a New Doppler-Echo Method for Quantification of Mitral Regurgitation

Start date:	Estimated completion date: Jun 93
Principal Investigator: MAJ David M. Mego, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): CPT Sheri Y. Nottestad, MC LTC John W. McClure, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
Total number of subjects enrolled to date: 24

Periodic review date: Review results:

Objective(s): To correlate the mitral regurgitant flow volume as determined by two techniques -- 1) the difference between angiographic and thermodilution stroke volumes at cardiac catheterization, and 2) a newly described method using the product of the mitral regurgitant color flow jet area and time velocity integral.

Technical Approach: Study will involve fifty patients of age greater than 18 years with mitral regurgitation who are undergoing diagnostic right and left heart cardiac catheterization. These patients will have no other significant regurgitant valvular lesions.

Progress: Study completed. 24 patients were enrolled, 18 of whom had technically adequate studies. Using a specimen rank order correlation,  $r=0.833$  for doppler color flow jet diameter and  $r=0.831$  for doppler-derived regurgitant volume, each as compared with angiographic grading of mitral regurgitation. These results have been presented to the American College of Physicians Army 10th Annual Scientific Meeting. A manuscript is in preparation.

### Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-93 Status: Ongoing

Title: Phase IV Study to Evaluate the Effect of Intravenous of Acute Hospital Admissions for Congestive Heart Failure

Start date:	Estimated completion date:
Principal Investigator: MAJ Landon Wellford, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 5  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy, safety, outcome, and length of stay for patients receiving intravenous milrinone compared to patients receiving dobutamine in the course of their hospital admissions for acute exacerbations of chronic heart failure.

Technical Approach: This is an open, parallel, randomized study of intravenous milrinone compared to dobutamine in patients who are admitted to the hospital with acute exacerbations of chronic heart failure. Study will include 125 cardiologists who will each treat a minimum of 4 patients for a total of approximately 500 patients. A three-month time period is allotted for the enrollment of the 4 patients.

Progress: We enrolled four patients as planned. All data collected and tabulated. All forms have been turned into data collection center. Study closed and results pending.



**Detail Summary Sheet**

**Date:** 15 Dec 93

**Protocol Number:** C-92-94

**Status:** Ongoing

**Title:** Colon Carcinogenesis: Modulation by Dietary Intervention

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> LTC Shailesh Kadakia, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Gastroenterology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 58  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To assess the modulation of cellular proliferation in colonic crypts (a biomarker of colon cancer risk) by dietary supplementation with cellulose in patients identified at higher than normal risk of developing malignant colon cancer. 2) To determine if longer term dietary intervention (1 year or more) of the same supplements will result in a significant reduction in the recurrence of adenomatous polyps in the colon.

**Technical Approach:** Study will be conducted using a prospective randomized control trial. Two dependent variables will be measured: 1) proliferative zone height (PZH), the biomarker previously discussed in the Background and Significance Section and 2) recurrence rate of sporadic adenomatous polyps. The dependent variable, cellulose supplementation will be composed of three levels: 0, 15, and 25 grams/day above normal baseline intake level.

**Progress:** Data collection is continuing and there are no reportable results at this time.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-95 Status: Completed

Title: Phonocardiogram Analysis: A Comparison of Several Methods of Signal Decomposition

Start date: Jun 92	Estimated completion date:
Principal Investigator: Mr. James R. Bulgrin	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): B. J. Rubal, Ph.D. LTC Joe M. Moody, MC
Key Words: Time-Frequency Analysis Phonocardiography	
Cumulative MEDCASE cost: \$2000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 6  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Compare and contrast several digital signal processing (DSP) methods in analyzing phonocardiograms (PCGs) obtained from patients with normal heart function and a variety of cardiovascular pathologies.

Technical Approach: In collaboration with time-frequency researchers at UTHSC, Brooks Air Force Base, University of Michigan and Hughes Air Craft Co., we have adapted off-shelf software or developed customized code to process intracardiac heart sound data.

Progress: Summary of final results. The work done for this protocol was published as "Comparison of Short-Time Fourier, Wavelet and Time-Domain Analyses of Intracardiac Sounds" in the Proceedings of the 30th Annual Rocky Mountain Bioengineering/Biomedical Sciences & Instrumentation Symposium.

This protocol will be closed and another protocol will continue the investigation begun in this protocol. The reasons for closing this protocol are: 1) no more intracardiac PCGs are forthcoming and 2) the next phase of external PCG analysis will be done in collaboration with Mr. Posch of Hughes Aircraft Co. Another class of time-frequency transforms, the so-called Cohen-class Time-Frequency Distributions, will be evaluated in terms of the PCG.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-97 Status: Ongoing

Title: Prospective Study of Clinical Efficacy of Two Formulations of Verapamil in Hypertensive Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ J. Grant Barr, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s): MAJ William Wright, MC
Key Words: Hypotension Calcium Channel Blocker	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine whether there are differences in efficacy, duration of action or side effects profiles of two different sustained release preparations of the calcium channel blocker. verapamil. The hypothesis is that there are no clinically significant differences in the two products and that their duration of action is similar.

Technical Approach: Prior to beginning of experimental phase of the study, patients will have objective and subjective data collected. Patients will not be on any calcium channel blocker during this period however, all medications they are taking will be recorded. Physical examination will include recording of blood pressure and informed consent will be obtained.

Progress: Study is ongoing. However, we have not enrolled patients as of yet.

### Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-98 Status: Ongoing

Title: Possible Etiology for Euthyroid Sick Syndrome

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Gerald Merrill, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Patients admitted to Brooke Army Medical Center (BAMC) who are seriously ill will potentially become candidates in the study. Judgement will be made by TRISS and APACHE III evaluation (an independent established method of objectively scoring patients) within 12 hours of admission to BAMC surgical or medical ICU by the staff physician involved in the study.

Technical Approach: Thyroid hormone levels and Triac/Tetrac levels will be tested in ICU patients at admission, as well as at 3 to 4 days and 2 weeks after admission. Subjects will vary as to their primary problem but all will be significantly ill. Analysis will be done to see if their clinical course and thyroid function tests correlate with Triac/Tetrac levels.

Progress: Dr. Merrill has had difficulty in the last year being able to isolate triac/tetrac.

### Detailed Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-01      Status: Ongoing

Title: Does Cholecystokinin (CCK) Prevent Gallbladder Sludge or Gallstone Formation in Patients Receiving Parenteral Nutrition? A Randomized Double-Blind Trial

Start date: 14 Oct 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Rashmikan B. Shah, M.D. Susan W. Wilson, M.S., R.D., L.P.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of cholecystokinin in preventing or reducing the incidence of gallbladder sludge and/or cholelithiasis formation in patients receiving total parenteral nutrition (TPN). The incidence of sludge and gallstones formation in the gallbladder will be determined in patients receiving either intravenous cholecystokinin or placebo.

Technical Approach: All patients started on TPN will be invited to participate. The presence of gallbladder sludge and gallstone will be evaluated by standard ultrasound (US) technique. Appropriate images will be obtained for each study to record the findings for later review.

Progress: There have been no patients enrolled since the protocol was approved.

### Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-02 Status: Ongoing  
Title: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Start date: Oct 92	Estimated completion date:
Principal Investigator: Carl S. Wrobleski, M.D.	Facility: Darnall Army Hospital & Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

Technical Approach: Eligible patients will have a FFS performed by physicians in either the Internal Medicine or Gastroenterology Clinics after proper counselling. A colon cleansing preparation consisting of two Fleet's one hour prior to the examination will be administered.

Progress: One-hundred patients completed survey appropriately; plan to double that amount to complete study. No complications.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-03                      Status: Ongoing

Title: 5-Fluorouracil Iontophoretic Therapy for Bowenoid Conditions

Start date: 26 Oct 92	Estimated completion date:
Principal Investigator: Martha L. McCollough, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Martin Giandoni, M.D. William Grabski, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the iontophoresis of 5-fluorouracil (5-FU) is an effective treatment for Bowen's disease and/or bowenoid actinic keratoses.

Technical Approach: As outlined in the protocol.

Progress: No patients have been enrolled in the study to date. The year was spent trying to obtain the equipment. The electrodes and machines were received end of 1993 and plans are to begin study in Jan 94.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-04                      Status: Completed

Title: Homeless Shelters as A Focal Source of Pulmonary TB

Start date: Sep 93	Estimated completion date:
Principal Investigator: Joseph T. Morris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): J. William Kelly, M.D. Curtis L. Yeager, Ph.D. Alice Sorro, RN, BSN Lawrence S. Higgins, M.D., FACP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 125  
 Total number of subjects enrolled to date: 125  
 Periodic review date: \_\_\_\_\_ Review results: Complete

Objective(s): The objectives of this protocol are to determine the prevalence of active M. tuberculosis pulmonary infections among homeless people in San Antonio who reside in two different homeless shelters and to examine the drug resistance properties of the M. tuberculosis strains which are isolated from infected individuals. These studies will begin to provide information to determine if characteristics of homeless individuals and/or the close conditions found in homeless shelters may contribute to an increasing prevalence of multiple-drug-resistant tuberculosis and in the rate of infection in general. If applicable, significant findings in these studies will be used in a subsequent protocol will test a small, cryopreserved portion of each sputum sample taken during these studies for use in a nucleic acid amplification-based rapid diagnostic procedure for M. tuberculosis infection. Technical Approach: This project will determine if there is significant rate of tuberculosis among homeless people who often reside in homeless shelters and if those strains of M. tuberculosis isolated are similar in their drug resistance properties. The authors believe that the overall poor health maintenance of homeless individuals, the crowded conditions common to homeless shelters, and the medical non-compliance of infected individuals living under these conditions are favorable factors in the growth, selection, and propagation of multiple-drug-resistant strains of M. tuberculosis.

Progress: 125 homeless residents and transients were tested for Mtb by sputum sample for culture. Only one positive (already diagnosed by the S.A. Health



C-93-04 (continued)

Dept) was found. Although sputum samples were preserved for PCR detection, the insignificant, low number of culture positives and the departure of the principal investigator to Madigan AMC, discouraged testing the samples by PCR. Project completed.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-05      Status: Ongoing

Title: A Comparison Study of the Prevention of Acute Aspirin Induced Gastroduodenal Injury with Omeprazole Versus Misoprostol

Start date: Mar 93	Estimated completion date: Jan 94
Principal Investigator: John J. McNerney, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): R. Shaffer, M.D. J. Carrougner, M.D. S. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 21  
Total number of subjects enrolled to date: 28  
Periodic review date: 1 Dec      Review results: See below

Objective(s): To compare the effect of omeprazole versus misoprostol in the prevention of aspirin induced gastroduodenal mucosal damage in healthy volunteers.

Technical Approach: As outlined the study protocol.

Progress: 28 subjects initially screened  
7 " excluded (3 abnl initial EGD/4 noncompliance)  
21 completed to date  
Misoprostol preventing erosions/ulceration vs placebo  
Omeprazole not significantly different vs placebo  
Need more subjects.

### Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-06 Status: Ongoing

Title: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Start date: Oct 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

Technical Approach: Patients undergoing a FFS in either the Internal Medicine Clinic at Darnall Army Community Hospital or the Gastroenterology Clinic at BAMC will be eligible for the study. Detailed exclusion data, etc, in protocol.

Progress: Since the approval of the protocol in Oct 92, most patients undergoing FFS at GI Svc have been handed out a questionnaire which is collected soon after the FFS is completed. Questionnaires have not been analyzed at the present time. Many of the questions have not been appropriately answered by the patients and will require telephone calls in order to obtain detailed information concerning those questions. We continue to collect the questionnaires in the same fashion.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-08                      Status: Ongoing

Title: Endosonoscopic Evaluation of Helicobacter Pylori Associated Gastritis

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: John G. Carrougher, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh Kadakia, M.D. Richard T. Shaffer, M.D. Michael D. Redwine, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: No significant findings

Objective(s): To determine if a sonographic pattern can be demonstrated in the gastric mucosa in patients with H. pylori associated gastritis. This information can help define the condition of H pylori gastritis and may assist the physician in the diagnostic difficulties seen with gastric wall abnormalities.

Technical Approach: The patient population will include all patients discovered to have H pylori infections as demonstrated by histology and/or urease test (clotest) during routine evaluation by the Gastroenterology Svc. The patients will then undergo endosonography followed by CT scan of the stomach wall. The EUS will be performed by the authors. The gastric wall will be examined using the UM3 endosonoscope from Olympus at frequencies of 7.5 and 15 MHZ. The gastric wall will be photographed in several areas during the EUS. CT scans will be photographed in several areas during the EUS. CT scans will be performed per routine of the radiology dept. Attempts will be made to assure adequate distention of the stomach during the CT scans and will be supervised by the radiologic staff. The radiology staff will be blinded to the results of the EUS. Gastric wall thickness will be measured by both modalities. All abnormal findings will be recorded. Patients may be collected from an preexisting protocol and will be studied prior to any antibiotic, or bismuth treatment.

Progress: Enrollment of patients is approximately one patient every two months.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-12                      Status: Ongoing

Title: ASGE Survey: Anticoagulation and GI Endoscopy

Start date: 3 Nov 93	Estimated completion date:
Principal Investigator: Carlos E. Angueira, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1,000 surveys  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To survey the practices of randomly selected gastroenterologists throughout the country regarding patients on oral anticoagulation or antiplatelet therapy and the way in which these medications should be adjusted prior to and following gastrointestinal endoscopy.

Technical Approach: Questionnaires addressing the management of patient on oral anticoagulants, antiplatelet therapy and NSAIDs in the periendoscopy period and strategies in dosage adjustments of these agents will be sent to approximately 1200 randomly selected members of the American Society of Gastrointestinal Endoscopy (ASGE) as well as the directors of all the gastroenterology training programs throughout the country. Reminder letters will be sent 30 and 60 days after the questionnaires to ensure the highest rate of return possible. These questionnaires will then be analyzed with a statistical program to establish recommendations based on the consensus of the obtained responses.

Progress: Data is still being analyzed for manuscript preparation.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-18      Status: Ongoing

Title: Monokine Induction in Patients Infected with Coccidioides Immitis

Start date: 16 Nov 92	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: SA Chest Hosp; WHMC Brooke Army Medical Center, Texas
Department/Service: Medicine/Infections Disease	Associate Investigator(s): Rebecca Cox, Ph.D. Matthew J. Dolan, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 12 (as of 30 Sep 93)\*  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether infection with the fungus Coccidioides immitis causes an increased production of the monokines tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-1 beta (IL-1B), and interleukin 6 (IL-6) in patients with coccidioidomycosis. Specific aims include the comparison of the in vitro monokine responses of blood monocytes from six study groups: patients with acute (primary) pulmonary coccidioidomycosis; patients with chronic, progressive pulmonary coccidioidomycosis; patients with disseminated coccidioidomycosis; patients with previously diagnosed but inactive coccidioidomycosis; and healthy, spherulin skin-test positive and skin-test negative controls.

Technical Approach: Description of subjects/controls; criteria for inclusion/exclusion; experimental design/methods; data collection; statistical analysis and specifics outlined in protocol.

Progress: Continuing to enroll patients and normal donors. Initial investigations into monokine production have been successfully completed. Ongoing investigations into the cytokine responses to infection with C. immitis are proving fruitful and a second manuscript is expectant.

\*Across the three participating institutions, 52 subjects were enrolled during the reporting period; 73 subjects have been enrolled to date.

Detail Summary Sheet

Date: 1 Dec 93

Protocol Number: C-93-19

Status: Ongoing

Title: An Open Protocol for the Use of Agrelin (Anagrelide) for Patients with Thrombocythemia

Start date: 9 Dec 92

Estimated completion date:

Principal Investigator:  
Timothy O'Rourke, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Hematology-Oncology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 1

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the safety and efficacy of Anagrelide in patients suffering from thrombocythemia of various etiologies.

Technical Approach: Inclusion/exclusion criteria; concomitant medications; drug supplies; screening and initial treatment along with other specifics given in protocol.

Progress: A single patient from protocol C-22-90 continues on this study. He has experienced no ill effects with good control of his platelet count and continues on study.

# Detail Summary Sheet

**Date:** 1 Dec 93      **Protocol Number:** C-93-22      **Status:** Completed

**Title:** A Pilot Study to Determine the Usefulness of Serum Nuclear Matrix Protein Measurement for Measuring Response to Chemotherapy

<b>Start date:</b> 9 Dec 92	<b>Estimated completion date:</b> Oct 93
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<b>Principal Investigator:</b> Howard Burris, III, M.D.	<b>Facility:</b> UTHSCSA; CTCR Brooke Army Medical Center, Texas
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<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	

<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>
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**Number of subjects enrolled during reporting period:** None at BAMC

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** 31 Dec 93      **Review results:** Closed

**Objective(s):** To determine the amount of release and the timing of the release of certain nuclear matrix proteins after treatment of lung cancer patients with chemotherapy.  
To obtain an indication of how many patients must be enrolled in a prospective "Cell death assay" study.

**Technical Approach:** Drug information, eligibility criteria, study design, registration guidelines, data submission and special instructions outlined in protocol.

**Progress:** The ten patients were treated at UTHSCSA and serum collected. Results are pending regarding the comparative results of the marker. Further studies will be planned based on these final results.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-24                      Status: Ongoing

Title: Comparison of the Effects of Nifedipine and Isradipine on Urinary Albumin Excretion and blood Pressure in Patients with Type Two Diabetes, Hypertension and Proteinuria

Start date: 4 Jan 93	Estimated completion date:
Principal Investigator: Kevin C. Abbott, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This trial will evaluate the effects of isradipine and a sustained release formulation of nifedipine, Procardia XL™, on arterial pressure and renal function. Renal function will be determined by twenty-four urine collections for creatinine clearance, fractional excretion of sodium, albumin and protein excretion.

Technical Approach: Subjects with type II diabetes with mild to moderate hypertension (defined in protocol) and urinary protein excretion of greater than one gram per twenty - four hours will be enrolled in the study. Age for eligibility will be 45 years or greater.

Progress: Six studies had to be disqualified due to improper processing in lab. Checking if these need to be redone or proceed.

Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-25 Status: Closed

Title: A Double-Blind Comparison of the Efficacy and Safety of Oral Granisetron (1 mg bid) with Oral Prochlorperazine (10 mg bid) in Preventing Nausea and Emesis in Patients receiving Moderately Emetogenic Chemotherapy

Start date: 7 Jan 93 Estimated completion date: 8 Sep 93

Principal Investigator: Howard A. Burris, III, M.D. Facility: Brooke Army Medical Center, Texas

Department/Service: Medicine/Hematology-Oncology Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost: Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 6  
Periodic review date: 31 Dec 93 Review results: Closed

Objective(s): To compare the efficacy of oral granisetron 1 mg bid with oral prochlorperazine (10 mg bid) mg over 24 hours and 7 days, in preventing nausea and emesis in patients receiving moderately emetogenic chemotherapy.

Technical Approach: Treatment regimen, chemotherapy, primary/secondary efficacy parameters, safety assessments and specifics given in protocol

Progress: A total of six patients were treated on this double-blind protocol, meeting our obligations to this multi-institutional study. The results have not yet been unblinded, so final comparison cannot be made. Overall, both treatment groups did reasonably well in the study.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-26      Status: Ongoing

Title: Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Anorexia Nervosa or Bulimia

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Neil Katz, M.D. Susan E. McManis, M.D., WHMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 7  
 Periodic review date: Review results:

Objective(s): To evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with anorexia nervosa or bulimia. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on empty into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying.

Technical approach: The importance of this project will be to demonstrate that erythromycin enhances gastric emptying in patients with anorexia and bulimia nervosa who have delayed gastric emptying. Since symptoms such as nausea, vomiting, abdominal pain, and early satiety may occur in these patients due to delayed gastric emptying, demonstration of faster gastric emptying after administration of erythromycin may provide therapeutic options in these patients.

Progress: To date approximately 7 patients have been enrolled in the study. Six patients have been enrolled that were referred to the principal investigator from the Psychiatric Svc at BAMC and one patient was referred from WHMC. The data has not been analyzed at present, however, overall impression is that Erythromycin has improved gastric emptying in all patients who received IV Erythromycin. In addition, most of the patients had abnormal gastric emptying at the baseline which either improved or became normal after receiving IV Erythromycin. There have been no side-effects referable to administration of

C-93-26 (continued)

Erythromycin. Serum motility levels have been sent to Florida for analysis, however, they have not been analyzed as of yet. Study is ongoing and we continue to enroll more patients as they are referred for entrance.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-27      Status: Ongoing

Title: A Randomized Phase I Trial of VP-16 with or without GM-CSF for the Treatment of Advanced Cancer

Start date: 4 Jan 93	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, M.D.	Facility: UTHSCSA Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Daniel D. VonHoff, M.D. Mace Rothenberg, M.D. Gladys I. Rodriguez, M.D. John Eckardt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 8  
Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To estimate the maximally tolerated dosage, and frequency and types of toxicities of etoposide when combined with rHuGM-CSF in patients with advanced malignancy. To determine which schedule of administration of rHuGM-CSF (prior to or during etoposide treatment) is superior in terms of the greater amount of etoposide delivered. To determine a recommended dosage and schedule for etoposide +/- rHuGM-CSF to be used in phase II trials. To document any responses which may be observed during treatment with the combined regimen. To evaluate the effects of rHuGM-CSF on the blood levels of etoposide administered orally.

Technical Approach: Background/rationale, patient eligibility, treatment plan, dosage and specifics in protocol.

Progress: A total of 39 patients have been enrolled to this 3-arm trial, and accrual continues. Toxicity has centered on reversible myelosuppression. The maximally tolerated dose in this study should be reached with the next cohort of patients.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-28                      Status: Ongoing

Title: Phase II Study of Brief Intravenous Adozelesin Infusion in Previously Untreated Extensive Small-Cell Lung Cancer

Start date: 29 Jan 93	Estimated completion date: May 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess whether adozelesin given as a monthly intravenous infusion produces objective clinical responses in adult patients with previously untreated extensive small cell lung cancer. To determine the qualitative and quantitative toxicity and reversibility of toxicity of adozelesin administered in this fashion.

Technical Approach: This trial will be an open label, non-controlled, non-randomized, single dose, multiple-course, multicenter study. Further details including subject selection, treatment, and dosage included in protocol.

Progress: Two patients have been entered on this study to date (1 at UTHSCSA and 1 at BAMC). (A total of 12 across all 5 participating US institutions.) Both patients were only able to take 1 cycle. Treatment delays due to prolonged myelosuppression resulted in both patients developing progressive disease. Accrual continues to a total of 20 patients to assess if toxicity is present in this disease with this drug.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-31      Status: Terminated

Title: Effect of Heparin Taper on Anti-Thrombin III in Patients with Acute Coronary Syndrome

Start date: Feb 93	Estimated completion date:
Principal Investigator: James J. King, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Dan Weiner, M.D. Bernard J. Rubal, Ph.D. Armistead L. Wellford, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Determine if tapering of heparin will affect antithrombin-III.

Technical Approach: Results will determine if tapering heparin therapy will decrease antithrombin III suppression which may minimize rebound hypercoagulability in patients with acute coronary syndromes.

Progress: Experienced difficulty in obtaining patients. Principal Investigator transferred to William Beaumont AMC.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-33      Status: Ongoing

Title: S<sub>2</sub> Triggered MUGA for Assessment of Diastole by LTC Michael D. Lecce, MC

Start date: Oct 92	Estimated completion date:
Principal Investigator: Michael D. Lecce, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D. Terry Bauch, M.D. James Heironimus, M.D. Neil Katz, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 8  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish the feasibility and potential clinical utility of Multi-Gated Blood Pool imaging using heart sounds as a trigger for image acquisition.

Technical Approach: The initial study will focus on: 1) The ability of this institution to use HSG for MUGA, 2) Compare the results of HSG Blood pool imaging to currently used technology and, 3) Establish institutional norms with the data acquired.

Progress: Several successful studies acquired; new sound transducer identified and use is in progress.



# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-34      Status: Terminated

Title: Gastric Intramucosal pH as a Predictor of Outcome from Trauma in the Adult Patient

Start date: Nov 93

Estimated completion date:

Principal Investigator:  
Mark D. Peacock, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Pulmonary Disease

Associate Investigator(s):  
David Ciceri, M.D.  
Patrick J. Offner

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): In a prospective, observational manner this project will assess the relationship between gastric intramucosal pH and outcome in adult trauma patients. We propose that a low pH is predictive of increased rates of multiple organ failure and mortality.

Technical Approach: A growing body of evidence indicates that conventional measures of resuscitation are not predictive of a good outcome in patients with a variety of severe illnesses, including trauma. Patient criteria and detailed specifics given in protocol.

Progress: This protocol should be terminated. It failed due to lack of support by the ER despite a number of efforts to improve their interest in the study. Additionally the complete replacement of the staff at the Critical Care Service of 13A has greatly reduced availability of physicians interested in completing this protocol.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-37      Status: Ongoing

Title: Proposal for Research Model to Investigate Possible Hormone Manipulations in the Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date: 19 Mar 93	Estimated completion date: Spring 94
Principal Investigator: Kevin Carlin, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Ron Kennedy Stephanie Anderson Isidoro Chapa John W. Kelly, M.D. Gerald Merrill/Albert Thomason, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): HIV's entrance into a cell and subsequent pirating of the intracellular mechanisms bypasses the usual steps in cellular function. HIV's ability to infect cells and/or take over the functions of the cell, may be facilitated and/or inhibited by various hormone levels. If this was found to be true perhaps a hormone manipulation could be designed to enhance therapy.

Technical Approach: Specifics are given in protocol.

Progress: Progress is being made with T cells infected with HIV showing independence to variable doses of thyroid hormone; data being presented to NIH/CDC sponsored retrovirus meeting in December 1993.

### Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-39 Status: Ongoing

Title: Relationship of Echocardiographic Doppler Indices of Diastolic Function to Severity of Cardiac Transplant Rejection

Start date: 24 Dec 02

Estimated completion date:

Principal Investigator:  
Sheri Y. Nottestad, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Cardiology

Associate Investigator(s):  
David M. Mego, M.D.  
Nancy Khan, BSN  
Bernard J. Rubal, Ph.D.

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 22 patients/42 studies

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Nov 93 Review results: Nov 93

Objective(s): To determine if serial changes in the echocardiographic Doppler A-Ar interval correlates with grades of cardiac transplant rejection.

Technical Approach: This study is a prospectively designed longitudinal study in which all cardiac transplant patients (n=25) on the transplant service at BAMC will be asked to participate. Following informed consent, 2-D doppler echocardiographic studies will be performed on patients undergoing routine right heart surveillance biopsies.

Progress: Data has been analyzed for all 42 studies performed to date on 22 patients. Early data analysis is encouraging for continuing the study. Presented at ACP meeting already.

# Detail Summary Sheet

**Date:** 1 Dec 93      **Protocol Number:** C-93-41      **Status:** Ongoing

**Title:** Alterations in Left Ventricular Systolic and Diastolic Function with Doxorubicin Therapy

<b>Start date:</b> 24 Dec 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Douglas G. Ebersole, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Cardiology	<b>Associate Investigator(s):</b> Terry Jenkins, M.D. Neil Katz, M.D. James Heironimus, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 3  
**Total number of subjects enrolled to date:** 3  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the effects of doxorubicin on left ventricular diastolic function and to determine if radionuclide angiographic and/or echocardiographic parameters of diastolic dysfunction reliably precede doxorubicin-induced systolic dysfunction reliably precede doxorubicin-induced systolic dysfunction. this could allow the clinician to adjust or discontinue doxorubicin therapy before potentially irreversible loss of systolic function occurs.

**Technical Approach:** It is proposed that to test the hypothesis that, in patients receiving doxorubicin therapy, radionuclide angiographic and echocardiographic markers of left ventricular diastolic dysfunction reliably precede the loss of left ventricular systolic function. Specifics in protocol.

**Progress:** Enrollment by Hem/Onc slower than expected.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-43      **Status:** Ongoing

**Title:** Effects of the Nicotine Patch on Esophageal Motility

<b>Start date:</b> 24 Jan 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Henri Renom DeLaBaume, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Gastroenterology	<b>Associate Investigator(s):</b> Shailesh C. Kadakia, M.D. Richard T. Shaffer, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 10  
**Total number of subjects enrolled to date:** 10  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine if the use of the nicotine patch has any effects on esophageal manometry studies.

**Technical Approach:** A total of 20 volunteers will be enrolled. These will consist of 20 healthy non-smoking adult volunteers. Age and sex will be noted for demographic data. Exclusion criteria will include pregnancy, chronic ETOH use, and any chronic medical conditions requiring medications that cannot be discontinued during the study period. Further details in protocol.

**Progress:** Preliminary results show decreased lower esophageal sphincter pressure at a significant rate.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-44      Status: Ongoing

Title: A Phase I Trial of Mitoxantrone Combined with Alpha-Interferon in Patients with Advanced Solid Tumors

Start date: 24 Jan 93	Estimated completion date: Jan 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Allison M. Thurman, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2 at BAMC

Total number of subjects enrolled to date: 2

Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximally tolerated dose of Mitoxantrone given intravenously every 21 days combined with a fixed subcutaneous dose of Alpha-Interferon in patients with advanced solid tumors. To determine the quantitative and qualitative toxicities of Mitoxantrone and interferon administered in combination. To determine the recommended dose for Mitoxantrone and Interferon on this schedule for Phase II trials. To collect information about the antitumor activity of Mitoxantrone and Interferon on this schedule.

Technical Approach: Drug information, eligibility criteria, treatment plan, dosage modifications and specifics outlined in protocol.

Progress: A maximally tolerated dose of 14 mg/m<sup>2</sup> for Mitoxantrone with 5 million units of Alpha-Interferon every 3 weeks was determined. Dose limiting toxicity consisted of myelosuppression with some mild flu-like symptoms. Activity was noted against renal cell, breast cancer and soft tissue sarcomas. Phase II trials are being written.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-45                      Status: Ongoing

Title: IND/IDE Trial of the Osteoport: A New Intraosseous Access Device

Start date: 27 Aug 92	Estimated completion date: May 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3 at BAMC  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the tolerance and clinical suitability of implanting the Osteoport™ in the iliac crest of patients who have failed at least one conventional venous access device. To determine the systemic bioavailability and the absorption rate profile of intraosseously (IO) administered morphine. To initiate an Experience of Use phase to determine longer term tolerance and estimated complication rates.

Technical Approach: Detailed specifics outlined in protocol.

Progress: A total of 8 patients were implanted with the Osteoport here in San Antonio, 24 participating, of which 3 were at BAMC. All three of the patients experienced clinical benefit with the device. Approval for this agent has been sent to the FDA and a manuscript has been submitted to the New England Journal of Medicine. Accrual will continue for an additional 6 months to gain more experience with the device.

# Detail Summary Sheet

**Date:** 1 Dec 93      **Protocol Number:** C-93-47      **Status:** Ongoing

**Title:** Validation of a Nonlinear Three Element Model for Estimating Stroke Volume and Aortic Flow Wave Form Morphology in Man

<b>Start date:</b> 24 Jan 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Bernard J. Rubal, Ph.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Cardiology	<b>Associate Investigator(s):</b> Karel H. Wesseling, Ph.D. John M. Karemaker, Ph.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:**      **Review results:**

**Objective(s):** To test the validity of at three-element nonlinear model for estimating aortic flow waveform morphology in man.

**Technical Approach:** This study will be a retrospective study in which flow waves derived from a three element non-linear Windkessel model<sup>2</sup> are compared to directly recorded electromagnetic flow/velocity waveforms. Details including data analysis included in protocol.

**Progress:** Progress on this project has been hampered by bioinstrumentation problems. It is anticipated this project will be completed by the end of 1994.



# Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-49 Status: Ongoing

Title: Monokine Production in Patients Infected with Mycobacterium Tuberculosis and Human Immunodeficiency Virus

Start date: 23 Dec 92	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: SA State Chest Hosp; Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Greg Anders, M.D. Rebecca A. Cox, Ph.D. Kenneth Kemp, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 7 (As of 30 Sep 93)\*

Periodic review date: Review results:

Objective(s): The goal of this investigation is to determine if tuberculosis causes an increased production of the monokines tumor necrosis factor-alpha (TNF-a), interleukin-1B (IL-1), and interleukin-6 (IL-6) in persons infected with the human immunodeficiency virus (HIV). The specific aims will be to compare the in vitro monokine responses of purified blood monocytes, total periphernuclear cells, and alveolar macrophages from four study groups: patients with concurrent Mycobacterium tuberculosis (MTB) and HIV infection; tuberculosis patients who are HIV-seronegative; patients with HIV infection without evidence of tuberculosis; and healthy, nontuberculous subjects who are seronegative for HIV.

Technical Approach: Description of subjects/controls, experimental design/methods, data collection and statistical analysis included in protocol.

Progress: Continuing to enroll normal donors for optimization of PCR techniques and for control cytokine production data. It is estimated that another 2-4 months of work to optimize the PCR procedures for the remainder of the cytokines will be necessary. During this time, lung tissue from patients with active tuberculosis (most expected to be at SASCH) will be obtained, snap frozen, and stored at -70°, in the anticipation of eventual in situ cytokine

C-93-49 (continued)

determinations.

\*Across the two participating institutions, 6 subjects were enrolled during the reporting period; 32 subjects have been enrolled to date.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-52      Status: Ongoing

Title: Gemcitabine as Palliative Therapy in Patients with Progressive Carcinoma of the Pancreas

Start date: 7 Dec 92	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4 at BAMC

Total number of subjects enrolled to date: 4

Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess the clinical benefit of gemcitabine therapy in patients with progressive cancer of the pancreas as measured by significant improvement in pain, performance status, or weight change. Also, to measure time to progressive disease, survival, objective tumor response rates, duration of clinical benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in these patients.

Technical Approach: Detailed specifics outlined in protocol.

Progress: Several patients have experienced significant clinical benefit from this new agent for pancreatic cancer. Toxicity has been minimal to date. Accrual to this multi-institutional trial should be completed within the next 1-2 months.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-53      Status: Ongoing

Title: Gemcitabine Versus 5-Fluorouracil in a Randomized Trial as First-Line Palliative Therapy in Patients with Carcinoma of the Pancreas

Start date: 7 Dec 92	Estimated completion date: Jun 94
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1 at BAMC

Total number of subjects enrolled to date: 3

Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To establish an advantage in clinical-benefit of gemcitabine over 5-fluorouracil (5-FU) in pain, performance status, or weight change. Also, to compare the treatment arms with respect to time to progressive disease, survival, objective tumor response rates, duration of clinical-benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in patients treated with gemcitabine and 5-FU.

Technical Approach: Detailed specifics in protocol.

Progress: Accrual has gone better than expected, and toxicity has been very manageable. A total of 84 out of a needed 105 have been accrued nationally. Preliminary results look favorable for gemcitabine. Patients randomized to 5-Fu on this trial may receive Gemcitabine on protocol C-93-52 when they develop progressive disease.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-54      Status: Ongoing

Title: A Phase I Trial of LY231514 Administered as a 30 Minute Infusion Every 7 Days"

Start date: 23 Mar 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date: 7  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximum tolerated dose of LY231514 administered as a bolus injection given every 7 days. To determine the qualitative and quantitative toxicities of LY231514 on this schedule. To determine the recommended dose of LY231514 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of LY231514. To collect information about the antitumor effects of LY231514.

Technical Approach: Specifics outlined in protocol.

Progress: This Phase I trial is complete with dose limiting toxicity developing sooner than anticipated. Myelosuppression occurred early in the treatment cycles and prevented all doses from being given on this schedule. Hints of activity were observed against colon cancer. A phase I trial utilizing an intermittent dosing schedule (every 3 wks) has already been initiated to increase dose intensity.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-55      Status: Closed

Title: A Phase II Trial of RP 56976 in Patients with Advanced Anthracycline Resistant Metastatic Breast Cancer

Start date: 23 Mar 93	Estimated completion date: Sep 93
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4 at BAMC  
 Total number of subjects enrolled to date: 5  
 Periodic review date: 31 Dec 93      Review results: Closed

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with anthracycline resistant metastatic breast cancer.

To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 56976 administered as an intravenous infusion over one hour every 21 days.

To determine the pharmacokinetics of RP 56976 in patients with metastatic breast cancer.

Technical Approach: Specifics outlined in protocol.

Progress: Outstanding antiplastic activity has been observed with an overall response rate of 56%. Toxicities included myelosuppression, peripheral edema and a mild dermatitis. Accrual is complete and phase III trials are being planned, along with an NDA submission to the FDA.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-56      Status: Ongoing

Title: Phase II Trial of RP56976 in Patients with Advanced Cutaneous Malignant Melanoma

Start date: 23 Mar 93	Estimated completion date: Mar 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 2  
Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with advanced cutaneous malignant melanoma previously untreated with cytotoxic chemotherapy.  
To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 56976 administered as an intravenous infusion over one hour every 21 days.  
To determine the pharmacokinetics of RP 56976 in patients with malignant melanoma.

Technical Approach: Detailed specifics in protocol.

Progress: Accrual continues to a total of 20 patients here in San Antonio (an additional 20 are being accrued on a "minor" trial with MD Anderson); 2 partial responses have been observed to date. Toxicities include myleo-suppression, peripheral edema and a mild dermatitis.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-57      Status: Ongoing

Title: A Phase I Bioavailability Study of Intravenous Versus Oral Hydroxyurea

Start date: 23 Mar 93	Estimated completion date: Jan 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To characterize the pharmacokinetic parameters (half-life, clearance, distribution) of orally and intravenously administered hydroxyurea. To determine the systemic availability of oral hydroxyurea.

Technical Approach: Specifics outlined in protocol.

Progress: Accrual is complete and results indicate the oral bioavailability of Hydroxyurea is 100% compared to the investigational intravenous form. Pharmacokinetics are being finalized and a manuscript is in preparation.



**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-58      **Status:** Closed

**Title:** A Pilot Study to Determine the Feasibility and Efficacy of Neoadjuvant Cisplatin, F-FU, and Leucovorin for Patients with Non-Small Cell Lung Cancer

<b>Start date:</b> 23 Mar 93	<b>Estimated completion date:</b> Sep 93
<b>Principal Investigator:</b> Howard A. Burris, III, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** 31 Dec 93      **Review results:** \_\_\_\_\_

**Objective(s):** To estimate the objective response rate, resectability rate, and proportion of patients free of microscopic residual lung cancer after treatment with cisplatin, 5-FU, and Leucovorin for three cycles.  
To assess the feasibility and toxicity of treating patients with stage II and III non-small cell lung cancer with cisplatin, 5-FU, and Leucovorin for three cycles followed by surgery and radiotherapy.

**Technical Approach:** Specifics outlined in protocol.

**Progress:** Trial was stopped prematurely because of a competing Southwest Oncology Group protocol - No plans for reactivation are being considered at this time.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-59      Status: Closed

Title: An Open, Ascending Dose Study Assessing the Safety, Tolerability and Pharmacokinetics of Subcutaneously Administered Recombinant Human Ciliary Neurotrophic Factor (rhCNTF) in Patients with Advanced Tumors

Start date: Sep 93	Estimated completion date: Sep 93
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0 at BAMC

Total number of subjects enrolled to date: 0

Periodic review date: 31 Dec 93      Review results: Closed

Objective(s): To assess the safety and tolerability of single dose range of 0.002 to 0.120 mg/kg with and without the concomitant use of chemotherapeutic agents in patients meeting the patient population criteria (see Materials and Methods: Selection of Patients section). Each patient will receive a single injection of rh CNTF 7-10 days prior to a course of chemotherapy and a second single injection of rhCNTF (at the same dose level) with a course of chemotherapy.

To collect pharmacokinetic data in this patient population over the rhCNTF dose range of 0.002 to 0.20 mg/kg with and without a course of chemotherapy. To assess for any interactions between rhCNTF and chemotherapy.

Technical Approach: Specifics outlined in protocol.

Progress: This study has been closed by the sponsor. No patients were accrued to this trial; accrual was difficult due to strict eligibility criteria. Alternate trials are being planned. (1 patient at UTHSCSA)

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-60      **Status:** Closed 24Sep93

**Title:** A Phase I Study of Intravenous Navelbine in Combination with Mitoxantrone in Patients with Refractory Solid Tumors

<b>Start date:</b> 23 Mar 93	<b>Estimated completion date:</b> Sep 93
<b>Principal Investigator:</b> Howard A. Burris, III, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 2  
**Total number of subjects enrolled to date:** 2  
**Periodic review date:** 31 Dec 93    **Review results:** Closed

**Objective(s):** To determine the maximally tolerated dose of intravenous NAVELBINE given on Day 1 and 8 in combination with a single dose of mitoxantrone (10 mg/m<sup>2</sup> on Day 1 and repeated every 21 days.  
To determine the quantitative and qualitative toxicities of intravenous NAVELBINE administered on a Day 1 and Day 8 schedule with mitoxantrone on Day 1.  
To determine the recommended dose for NAVELBINE and mitoxantrone on this schedule.

**Technical Approach:** Specifics outlined in protocol.

**Progress:** Trial complete with dose limiting toxicity of myelosuppression. Maximally tolerated dose - Mitoxantrone 10mg/m<sup>2</sup> day one and Navelbine 20 mg/m<sup>2</sup> day one and eight, repeated every 28 days. Phase II trials in advanced breast cancer are being indicated.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-63      Status: Closed

Title: Monokine Production During in vitro Infection of Human Monocytes with Leishmania donovani

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: James W. Martin, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The aim of the study is to determine the influence of *Leishmania donovani* infection, as a model of intracellular infection, on the production of the monokines tumor necrosis factor alpha (TNF- $\alpha$ ), interleukin-6 (IL-6), transforming growth factor-beta (TGF- $\beta$ ), and interleukin 10 (IL-10). Human monocytes from immunologically normal volunteers will be infected with amastigotes of *Leishmania donovani* and RNA extracted at intervals to determine message for production of the various monokines.

Technical Approach: This is descriptive study designed to show the kinetic monokine response of human monocytes in vitro to infection with *Leishmania donovani* for the monokines TNF, TGF, IL-6 and IL-10. Procedure and details outlined in protocol.

Progress: Doctor Martin PCSd to Eisenhower AMC - close protocol.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-64                      Status: Ongoing

Title: Effect of Omeprazole on Blood Alcohol Levels After Oral and Intravenous Ethanol

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Carole A. Buckner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Murray Francis, D.O. Shailesh Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date:                      Review results:                     

Objective(s): To determine whether or not omeprazole has an effect on blood alcohol levels after oral and intravenous ethanol in normal, healthy volunteers.

Technical Approach: Twenty-two male subjects between the ages of 21 and 50 who are eligible for medical care at BAMC will be enrolled. They will be non-smokers and will be social drinkers who consume no more than two liters of beer a week or no more than one drink per day. They will not be on Antabuse or Flagyl, and must not have used any H<sub>2</sub>-receptor antagonists in the previous 2 weeks. Study will be conducted in four phases as outlined in protocol.

Progress: Only five patients enrolled at time of this report, no progress yet.

# Detail Summary Sheet

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**Date:** 1 Dec 93      **Protocol Number:** C-93-65      **Status:** Ongoing

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**Title:** Effect of Supportive Interventions on Patient Perception of Musculoskeletal Pain During Cardiac Catheterization

<b>Start date:</b> 25 Mar 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Lois Miller, RN	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Cardiology	<b>Associate Investigator(s):</b> Sheri Y. Nottestad, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

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**Number of subjects enrolled during reporting period:** 18  
**Total number of subjects enrolled to date:** 18  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

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**Objective(s):** To test the effect of back and arm support interventions on the patients' perception of musculoskeletal pain during cardiac catheterization.

**Technical Approach:** There is a need to develop methods for reducing both the musculoskeletal pain and the consequent use of analgesics and narcotics to accomplish a level of comfort during cardiac catheterization. Details outlined in protocol.

**Progress:** Continuing enrollment and data collection.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-66      **Status:** Ongoing

**Title:** Myocardial Imaging Utilizing Positron Emission Tomography to Detect and Assess Coronary Artery Disease

<b>Start date:</b> 25 Mar 93	<b>Estimated completion date:</b> Unknown
<b>Principal Investigator:</b> Douglas G. Ebersole, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Cardiology	<b>Associate Investigator(s):</b> Landon Wellford, M.D. Neil Katz, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:**      **Review results:**

**Objective(s):** Evaluation of the accuracy and utility of Positron Emission Tomography in the detection and assessment of coronary artery disease.

**Technical approach:** Detailed specifics given in protocol.

**Progress:** Awaiting final approval from UTHSCSA PET center to begin enrolling patients.

# Detail Summary Sheet

**Date:** 1 Dec 93      **Protocol Number:** C-93-67      **Status:** Ongoing

**Title:** Evaluation of Diaphragmatic Function in Patients Receiving a Prolonged Course of High-Dose Prednisone for Interstitial Lung Disease

<b>Start date:</b> 25 Mar 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Daniel I. Loube, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Pulmonary Dis/Critical Care	<b>Associate Investigator(s):</b> James E. Johnson, M.D. H. M. Blanton, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 1  
**Total number of subjects enrolled to date:** 1  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine if high dose glucocorticoids lead to worsening diaphragmatic function in humans.

**Technical Approach:** Patient Selection, experimental design and procedures outlined in protocol.

**Progress:** One patient studied, mild decrement in diaphragm function. Staff associate on extended TDY. Upon return next month will enroll more patients.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-69                      Status: Ongoing

Title: Phase I Study of FCE 24517 in Adults with Advanced or Refractory Solid Tumors

Start date: 9 Apr 93	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To establish the maximally tolerated dose of FCE 24517 when given in divided doses intravenous daily x 3 every four weeks to adult patients with advanced and/or refractory solid tumors. To evaluate the acute toxicities and close limiting toxicity (DLT) of FCE 24517 in this patient population. To document any possible antitumor activity. Although a sufficiently sensitive, bioanalytical procedure for drug quantitation is not available at present, an attempt will be made to collect biofluid samples in order to explore possible concentration-response relationship.

Technical Approach: This is a dose finding study in patients with advanced and/or refractory tumors. The study will be open label and non-randomized. Based on preclinical toxicity data and Phase I Experience to date in europe, the initial starting dose of FCE 24517 will be 100 mcg/M, administered in three equally divided daily doses. The maximum tolerated dose level, based on single intravenous bolus injection, has not yet been determined based on European Phase I studies at doses up to and including 750 mcg/M<sup>2</sup>. Details included in protocol.

Progress: Accrual has been rapid; toxicities center around myelosuppression, without significant non-hematologic toxicity; maximally tolerated dose should be determined within the next 3-6 patients.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-70      **Status:** Ongoing

**Title:** Active Immunization of AZT-Treated HIV Infected Patients with Recombinant GP160 HIV Protein: Phase I/II Study of Immunogenicity, Toxicity, and Effect in "in vivo" Immunoregulation

<b>Start date:</b> 17 Nov 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> J. William Kelly, M.D.	<b>Facility:</b> DAH, and BAMC
<b>Department/Service:</b> Medicine/Infectious Disease	<b>Associate Investigator(s):</b> C. Kenneth McAllister, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 10  
**Total number of subjects enrolled to date:** 9  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To conduct a Phase 1/2 trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, gp160 candidate vaccine, in patients with HIV infection while on AZT. Specific objectives include: 1) to continue to evaluate the immunogenicity and toxicity of this product; 2) to determine the parameters predictive of immunoresponsiveness; and 3) to determine the clinical efficacy of immunization with gp160 in the treatment of HIV infection.

**Technical Approach:** As outlined in the study protocol.

**Progress:** Five volunteers were enrolled at BAMC and five enrolled at Ft Hood. One volunteer at Ft Hood failed to quality. The remaining volunteers continued the study. One developed an opportunistic infection during the course of the study. He is currently clinically stable. The study is ongoing.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-71      Status: Ongoing

Title: A Double-Blind, Placebo Controlled, Parallel Group, Multicenter Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium avium Complex Disease in HIV Infected People

Start date: 1 Apr 93	Estimated completion date:
Principal Investigator: J. William Kelly, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromized HIV infected patients with a CD4 count <100/ $\mu$ l.

Technical Approach: Selection of subjects, inclusion/exclusion criteria, study design, drug administration, etc. are outlined in protocol.

Progress: One patient has been enrolled and continues to do well on the study drug.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-72                      Status: Completed

Title: The Effect of Esophageal Dilatation on the Electrocardiogram

Start date: 1 May 93	Estimated completion date:
Principal Investigator: Brian Worley, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate prospectively whether esophageal dilatation produces significant EKG changes, whether ischemic or proarrhythmic and correlate these changes with blood pressure fluctuations.

Technical Approach: The null hypothesis is that esophageal dilatation will produce no significant EKG changes, whether ischemic or proarrhythmic, in those patients undergoing the procedure. Specifics given in protocol.

Progress: Found that patients with heart disease tend to have schemic changes on dilatation; those without heart disease tend not to have changes.

Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-73 Status: Ongoing

Title: A Phase II Study of Flutamide in Patients with Pancreatic Adenocarcinoma

Start date: 1 May 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: 31 Dec 93 Review results: Continue

Objective(s): To evaluate the clinical benefit of flutamide in patients with advanced pancreatic adenocarcinoma as evidenced by improvement in pain control, performance status, or nutritional status.

Technical Approach: Eligibility criteria, descriptive factors, response criteria, etc., covered in protocol.

Progress: Accrual continues - enrollment has been slow due to the debilitated states of advanced pancreatic cancer patients. No plans to change the design at present as this population is the most reasonable to be assessed at this time.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-74      Status: Ongoing

Title: A Phase I Dose Finding Clinical Trial to Evaluate the Safety and Pharmacokinetics of DMP 840 Given Daily for Five Consecutive Days (DX5) Every Four weeks in Cancer Patients with Refractory Solid Tumors

Start date: 6 May 93	Estimated completion date: 1 Jun 94
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words: DMP 840 Cancer Pharmacokinetics	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 7  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the maximum tolerated dose (MTD) and the recommended dose (RD) for subsequent Phase II trials of DMP 840. To determine dose limiting toxicities (DLTLs) of DMP 840, including qualitative and quantitative toxicities, and to define their duration and reversibility. To evaluate the pharmacokinetics of intravenous DMP 840 administered on single daily doses for five consecutive days, as related to toxicity. To document any antitumor activity observed.

Technical Approach: Inclusion/exclusion criteria, study procedures, safety parameters, study medications and other specifics outlined in protocol.

Progress: Utilizing this schedule, a maximally tolerated dose of 14.0 mg/m<sup>2</sup> was found in minimally pre-treated patients. Patients remain on study and tumor assessments are pending. To date, no partial or complete responses have been seen. The dose-limiting toxicity is myelosuppression.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-75      Status: Ongoing

Title: Phase I Evaluation of API-395 Administered Intravenously Every 14 Days

Start date: 6 May 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine maximum tolerated dose (MTD) of API-395 and to assess cumulative toxicity of repetitive cycles of treatment every 14 days; to collect information about antitumor effects of API-395; and characterize the toxicities associated with API-395 treatment.

Technical Approach: Study population, treatment plan, toxicities to be monitored, dosage modifications and specifics outlined in protocol.

Progress: Trial is due to begin enrollment in Feb 94. Delay has been due to the drug being unavailable.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-77                      Status: Ongoing

Title: High-Dose Chemotherapy and Total Body Irradiation with Autologous Stem Cell Support and Alpha Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis

Start date: 13 May 93	Estimated completion date:
Principal Investigator: W. Jeffrey Baker, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: May 94      Review results: \_\_\_\_\_

Objective(s): To assess the efficacy of fractionated total body irradiation, VP-16, and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis, low-grade lymphoma.

To assess the effect of post-transplant consolidation therapy with alpha interferon in patients who have achieved a complete response to high-dose chemoradiotherapy and ASCT.

To assess the prognostic value of serial monitoring of bcl-2 and bcl-1 gene rearrangements as markers of residual lymphoma cells.

Technical Approach: Eligibility criteria, treatment plan, drug information and specifics outlined in protocol.

Progress: The University of Texas Health Science Center at San Antonio has begun treating patients on a similar protocol and we will pool our data.



**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-79      **Status:** Ongoing

**Title:** The Effect of Bronchoalveolar Lavage Volume on the Diagnosis of Peripheral Primary Lung Cancer

<b>Start date:</b> 26 May 93	<b>Estimated completion date:</b> 1995
<b>Principal Investigator:</b> John F. Theroux, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Pulmonary Disease	<b>Associate Investigator(s):</b> James E. Johnson, M.D. W. Kenneth Linville, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 10  
**Total number of subjects enrolled to date:** 10  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine whether the use of a larger volume of brnchoalveolar lavage fluid increases the diagnostic yield of BAL cytology in peripheral, primary lung cancers.

**Technical Approach:** Patients undergoing FOB for evaluation of solitary lung masses will be asked to enroll. Of those that enroll, subjects will be included if they have no visible endobronchial disease during bronchoscopy and an ultimate diagnosis of cancer is made. Methods, data collection, statistical analysis, etc. included in protocol.

**Progress:** Ten patients enrolled, however, 2 excluded due to benign diagnoses and one due to visible endobronchial disease. Recruitment of patients continues.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-80                      Status: Ongoing

Title: The Effect of Omeprazole on Iron Absorption in Healthy Volunteers

Start date: 14 May 93	Estimated completion date:
Principal Investigator: John G. Carrougher, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): David A. Rinaldi, M.D.
Key Words:	Shaleish Kadakia, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the oral absorption of ferrous sulfate using the iron tolerance test is reduced in healthy volunteers during a state of reduced gastric acidity, as induced by the gastric proton pump inhibitor, omeprazole. To determine whether the absorption of ferrous sulfate can be improved using ascorbic acid during a state of reduced gastric acidity, as induced by omeprazole.

Technical Approach: Eleven healthy volunteers will be enrolled in the study. Specifics including inclusion/exclusion criteria, study outline, etc., outlined in protocol.

Progress: Original PI (Thomas Kepczyk) PCSd. More patients need to be studied.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-81      **Status:** Ongoing

**Title:** Occurrence of Obstructive Sleep Apnea in Pregnant Women and an Evaluation of Its Impact on Fetal Outcome

<b>Start date:</b> 13 May 93	<b>Estimated completion date:</b> Jul 94
<b>Principal Investigator:</b> Daniel I. Loubé, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Pulmonary Disease/Crit Care	<b>Associate Investigator(s):</b> Manuel L. Morales, M.D. Mark D. Peacock, M.D. Herman M. Blanton, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 300  
**Total number of subjects enrolled to date:** 300  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the incidence of obstructive sleep apnea (OSA) in pregnant women; and to evaluate the possible impact on OSA in pregnant women on fetal development and outcome.

**Technical Approach:** Statement of hypotheses, overview, experimental design, statistical analysis, etc, outlined in protocol.

**Progress:** Study indicates pregnant women snore significantly more than non-pregnant age matched women. This indicates increased upper airway resistance, which is epidemiologically related to OSA. However, we have only found two pregnant women with OSA, similar to what is expected in the normal population, but higher than previously reported for pregnancy (trend only).

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-83      Status: Ongoing

Title: High-Dose Taxol, Cyclophosphamide, and Cisplatin (Taxol/CPA/cDDP) with Autologous Bone Marrow Support (ABMS) for Metastatic Breast Cancer

Start date: 10 Jun 93	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7

Total number of subjects enrolled to date: 7

Periodic review date:      Review results:     

Objective(s): To determine the toxicity, time to marrow reconstitution, response rate and time to treatment failure of high-dose combination chemotherapy with taxol, cyclophosphamide and cisplatin, followed by autologous marrow infusion in eligible patients with metastatic breast cancer. To provide a new drug in combination with other chemotherapeutic agents in management of individual patients with advanced breast cancer.

Technical Approach: Patient eligibility, descriptive factors, treatment plan, etc, outlined in protocol.

Progress: All patients in remission; one expired 6 days after BM infused. Other patients tolerated treatment well.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-84      **Status:** Ongoing

**Title:** A Randomized Trial of Filgrastim at a Fixed Dose in Patients Undergoing Intensive Chemotherapy

<b>Start date:</b> 1 Jun 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Scott C. Martin, RPH	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b> Timothy J. O'Rourke, M.D. Svetislava J. Vukelja, M.D. Ralph F. Heaven, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b> 0	<b>Estimated cumulative OMA cost:</b> 0

**Number of subjects enrolled during reporting period:** 5  
**Total number of subjects enrolled to date:** 5  
**Periodic review date:** - **Review results:** -

**Objective(s):** Does G-CSF therapy starting 3 days post chemotherapy at a fixed 300 mcg dose prevent neutropenic febrile admissions in patients undergoing intensive chemotherapy treatment?

**Technical Approach:** Patient eligibility, study methodology, study medications, statistical analysis, etc, outlined in protocol.

**Progress:** Five patients enrolled as of 30 Sep 93. No adverse reactions noted. Enrollment slow but should pick up as TAMC starts to accrue patients.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-86      Status: Closed

Title: Taxol (NSC 125973) in Patients with Previously Treated Refractory Breast Cancer

Start date: 28 May 93	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To provide an investigational agent to physicians for the management of individual patients with advanced, refractory breast cancer who are not candidates for entry onto ongoing research clinical trials of higher priority.

Technical Approach: To observe the safety and efficacy of taxol 175/mg/m<sup>2</sup> when given as a 24 hour continuous infusion to patients with advanced breast carcinoma who have received at least two prior chemotherapy regimens for advanced disease and are no longer responding to therapy.

Progress: This study is closed. Two patients were entered under this compassionate use protocol.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-87      Status: Ongoing

Title: Phase I Study of Topotecan Administered on a Daily Times Five Schedule with a Single Infusion of Cisplatin Every Three Weeks to Patients with Advanced Non-Small Cell Lung Carcinoma

Start date: May 93	Estimated completion date: Mar 94
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Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
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Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
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Key Words:	
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Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
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Number of subjects enrolled during reporting period:	<u>1</u>
Total number of subjects enrolled to date:	<u>4</u>
Periodic review date: <u>31 Dec 93</u>	Review results: <u>Continue</u>

Objective(s): To determine the maximally tolerated dose (MTD) of topotecan administered on a daily times five schedule every 3 weeks with a single infusion of cisplatin.

To determine the quantitative and qualitative toxicities of topotecan administered on a daily times five schedule with cisplatin. Also to assess antitumor activity of topotecan in combination with cisplatin, including objective responses in patients with measurable disease.

Technical Approach: Study design, population, treatment, and detailed specifics outlined in protocol.

Progress: Excellent activity against advanced non-small cell lung cancer to date - toxicities have centered on myelosuppression. An additional 4 patients will be added to the maximally tolerated dose (Cisplatin 75 mg/m<sup>2</sup> day 1, Topotecan 1.0 mg/m<sup>2</sup> DI-5) to confirm tolerability.

# Detail Summary Sheet

**Date:** 1 Dec 93      **Protocol Number:** C-93-88      **Status:** Ongoing

**Title:** A Phase III Open-Label, Multicenter Trial of Actimmune Interferon Gamma-1b (rIFN-γ 1b) in Patients with Metastatic Renal Cell Carcinoma

<b>Start date:</b> 16 Jun 93	<b>Estimated completion date:</b> Apr 94
<b>Principal Investigator:</b> Howard A. Burris, III, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 1  
**Total number of subjects enrolled to date:** 1  
**Periodic review date:** 31 Dec 93      **Review results:** Continue

**Objective(s):** To determine the durable complete response rate (defined as a complete response of greater than 6 months' duration) of 100 µg of Actimmune administered subcutaneously once every 7 days to patients with metastatic renal cell carcinoma.

**Technical Approach:** Detailed specifics given in protocol.

**Progress:** Accrual continues; toxicity has been primarily fatigue/malaise; at least one objective response to date.



# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-89      Status: Ongoing

Title: A Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofosine Administered as a 120-Hour Infusion Every 21 Days to Patients with Ovarian Cancer

Start date: 16 Jun 93	Estimated completion date: Aug 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess the antitumor effect of five day (120-hr) infusion of intravenous ilmofofosine in patients with ovarian cancer; to assess the toxicity of ilmofofosine; to evaluate the serum concentration-time profile of ilmofofosine and the sulfoxide metabolite at steady state.

Technical Approach: Study population, inclusion/exclusion criteria, design, dosage, etc., outlined in protocol.

Progress: Patient enrollment is slow - being assessed in a very advanced stage group of Taxol/Cisplatin chemotherapy patients - but the trial will be completed as the agent looks very promising

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-90      Status: Closed 13Sep93

Title: Evaluation of Dynorphin A (1-10) Amide for the Relief of Intractable Cancer Pain

Start date: 21 Jun 93	Estimated completion date: Sep 93
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Closed

Objective(s): To evaluate the tolerability of dynorphin A (1-10) amide administered intravenously in three ascending doses to cancer patients in whom pain is unrelieved by large doses of opioids. To determine if dynorphin A (1-10) amide produces any pain relief in patients at these doses.

Technical Approach: Detailed specifics given in protocol.

Progress: Trial is complete and results are being assessed to plan future studies.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-91      Status: Ongoing

Title: A Randomized, Double Blind, Placebo-Controlled Study of Parallel Design to Evaluate and Compare the Therapeutic Implant 5FU-e TI (5003) to its Placebo Vehicle when Administered to Patients with External Condylomata Acuminata

Start date: 30 Jun 93	Estimated completion date: 30 Jun 94
Principal Investigator: Dirk M. Elston, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Jeffrey Stiles, M.D. Norvell Coots, M.D. Richard Vinson, M.D. Donna Corvette, M.D. Mark Peake, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: Annually/June Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of the Therapeutic Implant (5-FU-eTI 5003) with and without epinephrine, when administered in six weekly injections to male and female patients with external condylomata as compared to placebo gel (collagen). To describe the response rate, the time to recurrence and cumulative recurrence rate of condylomata in patients treated as outlined above. To evaluate the safety and efficacy of treatment in collagen skin test positive patients. Pharmacokinetics: To determine fluorouracil levels in plasma after initial injection in patients with a total wart area >199mm<sup>2</sup> (optional).

Technical Approach: Study design, inclusion/exclusion criteria, treatment plan and detailed specifics given in protocol.

Progress: Three patients undergoing treatment phase of protocol.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-92      Status: Ongoing

Title: A Phase I Trial of DS-4152 Administered as an Infusion Every 21 Days

Start date: 28 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximum tolerated dose of DS-4152 administered as an infusion every 21 days. To determine the qualitative and quantitative toxicities of DS-4152 on this schedule. To determine the appropriate dose of DS-4152 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of DS-4152.

Technical Approach: Patient eligibility, treatment plan, pharmacokinetics, toxicity, and specifics given in protocol.

Progress: Accrual continues - toxicity has been minimal, centering on prolongation of the APTT - and this effect has been ameliorated by prolonging the infusion junction. Patients now receiving the drug of a 16-24 infusion junction.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-96      **Status:** Ongoing

**Title:** An Open Phase II Trial of ICI D1694 in Subjects with Non-Small Cell Lung Cancer

<b>Start date:</b> 23 Jun 93	<b>Estimated completion date:</b> May 94
<b>Principal Investigator:</b> Howard A. Burris, III, M.D.	<b>Facility:</b> UTHSCSA; St. Luke's & Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 10  
**Total number of subjects enrolled to date:** 13  
**Periodic review date:** 31 Dec 93      **Review results:** Continue

**Objective(s):** To estimate the objective response rate (complete or partial response) of ICI D1694 in subjects with advanced non-small cell lung cancer. To characterize further the toxicity profile of ICI D1694.

**Technical Approach:** Subject selection including inclusion/exclusion criteria and other specifics given in protocol.

**Progress:** Two objective responses observed in the first 20 patients; accrual will continue to a total of 40 patients per protocol. Minimal toxicity noted to date.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-97      Status: Closed 5Jul93

Title: Phase II Trial of RP 56976 in Patients with Non Small Cell Lung Cancer Previously Treated with Platinum Based Cytotoxic Chemotherapy

Start date: 23 Jun 93	Estimated completion date: Jul 93
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 7  
 Periodic review date: 31 Dec 93      Review results: Closed

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with non-small cell lung cancer (NSCLC) previously treated with platinum based cytotoxic chemotherapy. To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 56976 administered as an intravenous infusion over one hour every 21 days.

Technical Approach: Design, dose regimen, duration of administration, number and selection of patients covered in protocol.

Progress: Accrual completed in July 1993 - a total of 31 patients were enrolled. An objective response rate of 30% was determined; toxicity consisted of myelosuppression, peripheral edema and dermatitis. Phase III trials are being planned.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-98      Status: Ongoing

Title: A Phase II Study of Intravenous Navelbine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 8  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess the clinical benefit of intravenous Navelbine in patients with hormone refractory prostate cancer (HRPC) as measured by time to disease progression, Karnofsky performance status, and pain palliation. To determine the objective response rate of intravenous Navelbine in those patients with HRPC and measurable disease. To evaluate the qualitative and quantitative toxicities of intravenous Navelbine in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration and specifics given in protocol.

Progress: Accrual of the first 20 patients is complete - 8 have experienced clinical benefit. Well-tolerated after starting dose decreased to 22.0 mg/m<sup>2</sup> (from 30 mg/m<sup>2</sup>). Additional patients will be enrolled until one combination trial with Navelbine/Estramustine is initiated.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-99      Status: Ongoing

Title: A Phase I Pharmacokinetic Study of Five Daily Intravenous and Oral Doses of Fludarabine Phosphate in Subjects with Advanced Cancer

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Timothy O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Karen J. Bowen, M.D. Patrick W. Cobb, M.D. John R. Eckardt, M.D. Gail Eckhardt, M.D. Terry Jenkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9 (3 at BAMC)  
 Total number of subjects enrolled to date: 9 (3 at BAMC)  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To characterize the pharmacokinetics of F-ara-A following 5 consecutive daily doses of fludarabine phosphate solution administered orally and intravenously.  
 To characterize the relative incidence severity and duration of clinical and laboratory adverse events observed in these subjects during study. To compare plasma and urine metabolites after intravenous and oral administration of fludarabine phosphate solution.

Technical Approach: Rationale, study design, inclusion/exclusion criteria, and detailed specifics outlined in protocol.

Progress: A total of nine patients have been entered with three at BAMC. No untoward side effects have occurred and the study is ongoing.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-100                      Status: Ongoing

Title: A Pilot Study of the Safety and Efficacy of an Intralesionally Administered Cisplatin Therapeutic Implant (MP 5010) in Patients with Superficially Accessible Tumors of Any History

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 4  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To evaluate the safety and efficacy of the intratumorally administered CDDP TI (MP 5010) in patients with superficially accessible tumors of any history. To observe the tumor responses, and investigate the potential for efficacy and local disease control. To observe the duration of responses, and where biopsy is feasible and accepted by the patient, to observe the effects of intralesional MP 5010 on the histopathology of injected lesions that respond.

Technical Approach: Study design, patient selection criteria, treatment plan, doses, toxicity, etc, outlined in protocol.

Progress: Accrual relatively slow - very specific patient population. Clinical benefit has been observed in most patients treated to date. Enrollment continues to gain better experience.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-101      Status: Terminated

Title: A Double-Blind, Placebo-Controlled Study of Masoprocol Cream (10%) for the Treatment of Small Acetowhite Lesions of Condylomata Acuminata of the Penis

Start date: Jun 93	Estimated completion date:
Principal Investigator: Dirk M. Elston, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To attempt to establish efficacy of masoprocol cream for the treatment of small acetowhite lesions of condylomata acuminata (lesions 1 mm or less, poorly visible except with acetowhitening).

Technical Approach: Approximately 30 patients with external small (<1 mm) acetowhite lesions of condylomata acuminata will be randomized to receive either placebo vehicle or masoprocol cream (10%). To be eligible for the study, patients must have no other genital lesions and must not have received other treatment for their condylomata during the preceding 2 months. Further outlined in protocol.

Progress: Study cancelled. Drug company unwilling to provide drug because of recent reports of contact dermatitis.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-102                      Status: Ongoing

Title: The Risk of Hemorrhage in Patients with Interstitial Lung Disease Undergoing Transbronchial Lung Biopsy

Start date: 1 Jul 93	Estimated completion date:
Principal Investigator: Michael J. Morris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease & Crit Care	Associate Investigator(s): Mark D. Peacock, M.D. David Mego, M.D.
Key Words: Hemorrhage, interstitial lung disease, transbronchial biopsy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13  
 Total number of subjects enrolled to date: 13  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): In a prospective manner this project will determine the incidence of clinically occult pulmonary hypertension (PH) in patients with interstitial lung disease (ILD). Subsequently, the rates of hemorrhage following transbronchial lung biopsy (TBBx) in patients with interstitial lung disease will be compared with regards to the presence or absence of clinically occult PH. We propose that PH detectable only by echocardiography does not increase the risk of hemorrhage during TBBx.

Technical Approach: The hypothesis to be tested is that PH, that is not clinically evident by physical exam and radiographic evaluation, but detectable by echocardiography does not cause increased hemorrhagic complications from transbronchial biopsies. Further specifics in protocol.

Progress: 13 patients have been enrolled into study. There have been no bleeding complications (all patients have had minimal bleeding), although several patients have had mild increase in pulmonary systolic pressures.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-104                      Status: Ongoing

Title: Phase I Trial of VP16 + AMGEN rG-CSF in Patients with Advanced Malignancies

Start date: 30 Jul 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. David A. Rinaldi, M.D. Patrick Cobb, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximally tolerated dose and toxicities of VP16 when combined with r-G-CSF in patients with advanced malignancies.  
 To determine which schedule of administration of r-G-CSF and VP16 is superior in ameliorating toxicity while maximizing potential synergy of the two agents.  
 To determine the recommended dose and schedule of VP16 + r-G-CSF to be used in phase II trials.  
 To document any responses that may occur with this combination.

Technical Approach: Design/methods, subject population, recruitment and other specifics outlined in protocol.

Progress: Not initiated yet as separate IND for G-CSF but to be obtained - filed and approval pending.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-105                      Status: Ongoing

Title: Phase I Trial of CT-1510R in Patients with Advanced Refractory Cancer Undergoing Therapy with High-Dose Thiotepa

Start date: 29 Jul 93	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximum tolerated concentration (MTC) of orally administered CT-1501R in patients with advanced refractory cancer. To determine the pharmacokinetic (PK) profile of CT-1501R including the elimination plasma half-life ( $T_{1/2}$ ), area under the curve (AUC), and plasma clearance ( $C_L$ ) following the first and last dose of CT-1501R during the MTC/PK period.  
 To determine the pharmacokinetic profile of CT-1501R during treatment with thiotepa and the effect of CT-1501R on thiotepa pharmacokinetics.

Technical Approach: Study design, patient selection, treatment definition, adverse experience, data analysis and other specifics outlined in protocol.

Progress: Active accrual underway - patients are being entered on the third dose level. The agent has been well-tolerated thus far.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-106      Status: Closed 26Jan93

Title: A Phase II Trial of DaunoXome in Patients with Advanced Adenocarcinoma of the Colon

Start date: 29 Jul 93	Estimated completion date: Jan 93
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Closed

Objective(s): To determine the activity of DaunoXome in patients with advanced colorectal carcinoma.  
 To evaluate the qualitative and quantitative toxicities of DaunoXome.

Technical Approach: Staging criteria, eligibility criteria, treatment plan, toxicities to be monitored/dosage modifications, etc, outlined in protocol.

Progress: Accrual of 20 patients completed - no objective responses observed, and no further plans for development of DaunoXome in this disease type.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-115      Status: Ongoing

Title: Obstructive Sleep Apnea and Silent Myocardial Ischemia in Post-Myocardial Infarction Patients: frequency, temporal relationship, and response to nasal continuous positive airway pressure (nCPAP) therapy

Start date: Aug 93	Estimated completion date: Aug 94
Principal Investigator: Terry D. Bauch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology/Pulm Disease	Associate Investigator(s): Daniel I. Loube, M.D. Mark D. Peacock, M.D. James K. Gilman, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Identify obstructive sleep apnea (OSA) in post-myocardial infarction(MI) patients with known risk factors for OSA. 2) Investigate the frequency of, and temporal relationship between episodes of OSA and Silent Myocardial Ischemia (SMI) in post-MI patients. 3) Determine the effect of nCPAP treatment of OSA upon SMI in post-MI patients.

Technical Approach: Subjects, methods, data collection, statistical analysis, etc., outlined in protocol.

Progress: One patient enrolled. Ten potential subjects identified, enrollment in progress.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-117      **Status:** Ongoing

**Title:** A Phase II Study of Gemcitabine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

<b>Start date:</b> Aug 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Howard A. Burris, III, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** 31 Dec 93      **Review results:** Continue

**Objective(s):** To assess the clinical-benefit of intravenous gemcitabine in patients with hormone-refractory prostate cancer (HPRC) as measured by Karnofsky Performance Status (KPS), and pain palliation.

**Technical Approach:** Investigational plan, study population, dosage & administration, concomitant therapy and other specifics covered in protocol.

**Progress:** Patient enrollment has been recently enacted - too early to assess activity of this agent in this disease.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-118                      Status: Ongoing

Title: A Double-Blind Randomized Parallel Study of the Antiemetic Effectiveness of IV Dolasetron Mesylate vs. IV Zofran in Patients Receiving Cisplatin Chemotherapy

Start date: 5 Aug 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To compare the effectiveness of a 2.4 mg/kg single intravenous (IV) dose of dolasetron mesylate to a 32 mg single intravenous (IV) dose of ondansetron (Zofran<sup>®</sup>--Glaxo) for complete prevention of emesis due to > 70 mg/m<sup>2</sup> of cisplatin chemotherapy. Secondary objectives will be to compare the effectiveness of a 1.8 mg/kg single intravenous (IV) dose of dolasetron mesylate to a 32 mg single intravenous (IV) dose of ondansetron (Zofran<sup>®</sup>--Glaxo) and to the 2.4 mg/kg single IV dose of dolasetron mesylate for complete prevention of emesis due to > 70 mg/m<sup>2</sup> of cisplatin chemotherapy.

Technical Approach: Study design, materials/methods and specifics outlined in protocol.

Progress: Expected enrollment of 10 patients completed quickly - because of double-blind nature of the study, no efficacy results can yet be assessed.

### Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-119 Status: Ongoing

Title: Prospective Single-Blinded Cross-Over Comparison of Fosinopril and Nifedipine in Hypertensive Patients

Start date: Oct 93	Estimated completion date:
Principal Investigator: Edward C. Michaud, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Internal Medicine	Associate Investigator(s): J. Grant Barr, M.D. Steven F. Gouge, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether there are differences in efficacy, duration of action, or side effects profiles, of two commonly used antihypertensive agents nifedipine and fosinopril. The hypothesis is that there are no clinically significant differences in the two products and that their duration of action is similar.

Technical Approach: The study will gather data by the use of 24 hour blood pressure monitors, blood sampling for basic electrolytes, Blood Urea Nitrogen, Creatine, Liver Function Tests, and patient questionnaires to be filled out by physician at interview. Details are outlined in protocol.

Progress: Due to time constraints, study will not start until October 1993.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-122                      Status: Ongoing

Title: A Single Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris

Start date: Oct 93	Estimated completion date: Jul 94
Principal Investigator: Tracey Biediger, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Dirk M.Elston, M.D. Mark Peake, M.D. Rick Keller, M.D. Leo Conger, M.D.
Key Words: Acne Retin-A	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads and whiteheads) acne vulgaris.

## Technical Approach:

Progress: Power analysis statement: Estimating the efficacy of Retin-A cream at 80% with a 20% standard deviation, we want to be able to detect a 30% difference (equal to 1 and 1/2 standard deviations). Using a method published by Kraemer and Thiemann, we will need 9 subjects per group (nightly versus every other night versus weekly application) for a 95% level of confidence and power of 80%. The test is an Analysis of Variance followed by a one-tailed test corrected for multiple comparisons.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-124      **Status:** Ongoing

**Title:** The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Heart Disease and LV Dysfunction

<b>Start date:</b> 14 Sep 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> James K. Gilman, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Cardiology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b> N/A	<b>Estimated cumulative OMA cost:</b> N/A

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** N/A      **Review results:** N/A

**Objective(s):** To determine whether d-sotalol on Mortality in Patients with Atherosclerotic Heart Disease and LV Dysfunction (resting LV ejection fraction < 40%) and CHD.

To compare the safety and tolerance of d-sotalol with placebo when administered long-term to patients with LV dysfunction (resting LV ejection fraction < 40%) and CHD.

**Technical Approach:** Study design/eligibility, safety and specifics outlined in protocol.

**Progress:** All final approvals obtained. Drug is in pharmacy. Hope to enroll first patient soon.

# Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-125 Status: Ongoing

Title: Endosonics PTCA Balloon Catheter: Eagle

Start date: 14 Sep 93	Estimated completion date:
Principal Investigator: William T. Wright, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To evaluate the safety and efficacy of the device. In addition to achieving this objective, the study will supplement the growing body of knowledge concerning the procedure, assisting physicians with some of its technical aspects, aiding them in selecting candidates most likely to benefit from the procedure, and providing them with comprehensive data to use in comparing this form of therapy for coronary artery disease to the presently available alternatives.

Technical Approach: Patient selection, risk analysis and specifics are outlined in protocol.

Progress: Waiting for catheter shipment from Endosonics Corporation.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-126      Status: Ongoing

Title: Patterns of Intraventricular Flow During Isovolumic Relaxation During Normal Excitation and Right Ventricular Pacing Under Different Loading Conditions

Start date: Aug 93	Estimated completion date: Feb 94
Principal Investigator: Robert W. Price, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): John W. McClure, M.D. Joe M. Moody, Jr., M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost: N/A	Estimated cumulative OMA cost: N/A

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 3  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To characterize intraventricular flow patterns by Doppler echocardiography during normal activation, right ventricular pacing, and altered loading conditions.

Technical Approach: The study will include 30 patients who have had a permanent transvenous pacemaker placed, either a right ventricular or a dual chamber leads for established clinical indications. Volunteers for this study will be chosen from patients in the Pacemaker Clinic who meet criteria given in protocol.

Progress: Recently enrolled 2nd and 3rd subjects. Will be studying 2-3 per week until pool is exhausted. Have seen the expected effect in each patient studied so far.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-127      **Status:** Closed 6Dec93

**Title:** The Effect of Subcutaneous r-HuEPO in Patients with Chronic Lymphocytic Leukemia

<b>Start date:</b> 27 Sep 93	<b>Estimated completion date:</b> Dec 93
<b>Principal Investigator:</b> Howard A. Burris, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** 31 Dec 93      **Review results:** Closed

**Objective(s):** To determine the effect of subcutaneous r-HuEPO on hematocrit and quality of life in anemic, chronic lymphocytic leukemia patients.

**Technical Approach:** Patient selection, procedures, management etc., outlined in protocol.

**Progress:** Study closed due to lack of suitable patients - very few CLL patients with severe anemia. Other study sites probably had the same problem.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-129                      Status: Ongoing

Title: A Phase II Study of MGBG in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 21 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: UTHSCSA; CTRCofSA; & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Suzanne M. Fields Daniel D. Von Hoff, M.D. Geoffrey Weiss, M.D. John R. Eckardt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess the clinical benefit of intravenous MGBG in patients with hormone refractory prostate cancer (HRPC) as measured by time to disease progression, Karnofsky performance status, and pain palliation.  
 To determine the objective response rate of intravenous MGBG in those patients with HRPC and measurable disease.  
 To evaluate the qualitative and quantitative toxicities of intravenous MGBG in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration, etc, covered in protocol.

Progress: Accrual is underway - dosing may be too intense based on the 1st live patients - schedule being altered to drop the day 8 dose due to mucositis. Plan to enroll a total of 20 patients.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-130                      Status: Ongoing

Title: Phase I Trial of Escalating Doses of Continuous Infusion Topotecan followed by Etoposide

Start date: 22 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximal tolerated dose of the combination of the Topoisomerase I and II inhibitors topotecan and etoposide. To determine the qualitative and quantitative toxicities of topotecan and etoposide on this schedule. To determine the recommended dose for topotecan and etoposide on this schedule for Phase II trials. To collect information about antitumor affects of topotecan and etoposide on this schedule.

Technical Approach: Patient eligibility, plan of the study and other specifics are outlined in protocol.

Progress: Dose limit toxicity has been observed in both the heavily and minimally pretreated patients, primarily neutropenia and thrombocytopenia. Accrual is being completed to confirm the tolerability of the recommended phase II dose.

### Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-131 Status: Ongoing

Title: Phase III Trial of rhu GM-CSF in Patients with Febrile Neutropenia Following Cancer Chemotherapy

Start date: 22 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: 31 Dec 93 Review results: Continue

Objective(s): To evaluate the effect of rhu GM-CSF on days from initiation of study medication to the first of three consecutive measurements of ANC > 500 cells/mm<sup>3</sup> and temperature < 38.0°C.

Technical Approach: Study design, patient eligibility, study drugs, and specifics are outlined in protocol.

Progress: Enrollment is underway; double-blinded so no results to date. No problems with trial design.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-132      Status: Ongoing

Title: A Safety, Antiemetic Efficacy and Pharmacokinetic Study of Single Dose IV RS-25259-197 in Cisplatin-Naive Cancer Patients Receiving High-dose Cisplatin

Start date: 23 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0 at BAMC  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the lowest dose of RS-25259 that produces complete control of emesis in at least 7 of 10 cancer patients receiving high-dose cisplatin.

To determine the maximum dose at which at least 4 of 5 patients receiving high-dose cisplatin do not suffer significant adverse events, and the minimum dose at which at least 4 of 5 patients have 2 or fewer emetic episodes in 24 hours (complete or major response).

To study the pharmacokinetics of single IV doses of RS-25259 in this patient population.

Technical Approach: Selection of patients, study medication/design, etc., are outlined in protocol.

Progress: No patient has been enrolled (drug did not become available until Nov 93) - accrual continues.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-133                      Status: Ongoing

Title: Phase II Trial of RP 56976 in Patients with Cholangiocarcinoma

Start date: 24 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Patrick W. Cobb, M.D. John R. Eckardt, M.D. Suzanne Fields, Pharm.D. Stephen Kalter, M.D. John G. Kuhn, Pharm.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess whether taxotere given as an every three week intravenous infusion procedures objective clinical responses in patients with cholangiocarcinoma.

To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous taxotere.

Technical Approach: Design, dose regimen, number and selection of patients, and other specifics are outlined in protocol.

Progress: No initiation yet - investigation IND pending.

# Detail Summary Sheet

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**Date:** 1 Dec 93                      **Protocol Number:** C-93-134                      **Status:** Ongoing

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**Title:** Prospective Correlative Clinical Trial of Response to Taxol in a Newly Developed Chemoresponse Assay Versus Clinical Response to Taxol in Patients with Ovarian Cancer

<b>Start date:</b> 27 Sep 93	<b>Estimated completion date:</b> 12/94
<b>Principal Investigator:</b> Howard A. Burris, III, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology-Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

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**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** 31 Dec 93      **Review results:** Continue

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**Objective(s):** To conduct a prospective correlative clinical trial of the newly developed ChemoResponse Assay in patients with ovarian cancer. This clinical trial should definitely answer the question as to whether the ChemoResponse Assay has applications in the care of patients with ovarian cancer.

**Technical Approach:** Patient eligibility, overall trial design, study calendar, statistical considerations and other specifics are covered in protocol.

**Progress:** Trial is now open for accrual - no patients enrolled to date.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-135                      Status: Ongoing

Title: Dose Ranging, Randomized, Multicenter Study of Synercid (RP57669/RP54476) Vs. Vancomycin in the Treatment of Central Catheter-Related Gram-Positive Bacteremia

Start date: 27 Sep 93	Estimated completion date: Jun 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA; CTCofSA; Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Karen Bowen, M.D. Patrick W. Cobb, M.D. Gail Eckhardt, M.D. Stephen Kalter, M.D. Jim Koeller, M.S.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To evaluate the efficacy and safety of two different dosing regimens of Synercid compared with vancomycin hydrochloride (Vancocin HCl Lilly) when administered for 5 to 14 days in the treatment of patients with central catheter-related Gram-positive bacteremia.

Technical Approach: Patient definition, plan of the study, clinical and laboratory procedures and detailed specifics outlined in protocol.

Progress: No patient enrolled - drug became available in Dec 93 - accrual continues.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-136      Status: Ongoing

Title: Phase II Trial of RP 5676 in Patients with Advanced Epithelial Ovarian Cancer Refractory to Treatment with Cisplatin and/or Carboplatin Chemotherapy

Start date: 27 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with epithelial ovarian cancer refractory to platinum based chemotherapy.

To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 5697 administered as intravenous infusion over one hour every 21 days.

Technical Approach: Patient eligibility, plan of the study, efficacy and safety measurements, etc, are outlined in protocol.

Progress: Difficult patient population, accrual very slow, very specific patient population (Cisplatin - refractory). A total of 10 patients enrolled with at least three objective responses.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-137                      Status: Ongoing

Title: A Phase II Trial of CPT-11 in Patients with Metastatic Colorectal Carcinoma

Start date: 30 Sep 93	Estimated completion date: Jan 94
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Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
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Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	

Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
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Number of subjects enrolled during reporting period: 8

Total number of subjects enrolled to date: 8

Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): The primary objective of this study is to estimate the antitumor activity (response rate) of CPT-11 in patients with metastatic colorectal carcinoma that has recurred following 5-FU-based therapy. The secondary objectives of this study are to evaluate the onset and duration of antitumor responses and to evaluate the qualitative and quantitative toxicities of CPT-11.

Technical Approach: Drug information, background/rationale and specifics outlined in protocol.

Progress: Accrual complete - at least 20% objective response rate to date - tolerability improved after study dose decreased from 150 to 125 mg/m<sup>2</sup>.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-103-90                      Status: Completed

Title: Childhood Cancer: Coping of Child and Parent and Correlates  
(Collaborative Study with University of Texas Health Science Center).

Start date: 10 Oct 90	Estimated completion date:
Principal Investigator: Gail Hoevet, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: University of Texas Health Science Ctr.	Associate Investigator(s): Jean Johnson, Ph. D., R.N.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: 60  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To refine stress coping instruments for children with cancer and for their parents that were developed during the first phase of this program.

Technical Approach: Subjects will be identified in Children's Cancer Clinics a BAMC and Santa Rosa Medical Center. The children will be male or female between the ages of 6 and 14 with a diagnosis of leukemia, lymphoma or malignant tumor either the diagnosis, treatment or completion of treatment stage of the illness. Parents of these children will comprise the parent sample. Completion of the stress and coping, self concept and temperament questionnaires may take place in the subjects homes or in the clinic, whichever is most convenient.

Progress: Data collection and analysis at BAMC is completed.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-18-91                      Status: Terminated

Title: Nursing Intervention Lexicon and Taxonomy Study.

Start date: 15 Jan 91	Estimated completion date:
Principal Investigator: Susan J. Grobe, U.T. Austin	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s): Marsha Fonteyn, RN, MSN
Key Words:    Nursing interventions Natural language analysis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13  
Total number of subjects enrolled to date: 94 includes nurses from other sites  
Periodic review date: 4 Jan 93                      Review results: \_\_\_\_\_

- Objective(s): 1) What are the typical nurses intervention statements identified by nurses for chronically ill adult patients?
- 2) What information is used by nurses to formulate nursing intervention statements?
- 3) What are the patterns of information selected by nurses to formulate nursing intervention statements about chronically ill adult patients?

Technical Approach: Both the mathematical (COBWEB) and a semantics based (ID-3) approach to classification of the nursing interventions has been taken. The ID-3 approach resulted in a preliminary result of 89.5% accuracy in classification. Rules modification will be undertaken to improve the expert system's classification.

Progress: Study terminated due to principal investigator's departure from Brooke Army Medical Center.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-42-91 Status: Terminated

Title: The Use of Physical Restraints in Hospitalized Elderly.

Start date: 2 Apr 91	Estimated completion date:
Principal Investigator: Mary Ann Matteson, Ph. D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s): Jean Johnson, Ph. D., R.N.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25  
 Total number of subjects enrolled to date: 25  
 Periodic review date: Review results:

Objective(s): To determine the risk factor and consequences related to the use of physical restraints in hospitalized older adults and to identify the nurses' rationale for the type and extent of use of physical restraint.

Technical Approach: This is a prospective, descriptive study that will consist of collecting data regarding hospitalized patients who are physically restrained, the restraints used, and the immediate physiological and psychological effects of the restraints. A control group of patients who are not restrained will be used to compare the differences. In addition, a questionnaire will be given to nurses to determine their reasons for using physical restraints.

Data will be obtained from the charts to determine demographic information, medical diagnoses and medications. Subjects will be given the Folstein Mental Status Exam, and the Rosenberg 10-item Self-Esteem Scale. The investigators will check the patient's skin for the presence of pressure sores and note the stage and size, take vital signs, obtain height and weight, assess activities of daily living (ADL) performance and assess pulmonary function (SaO<sub>2</sub>) using a pulse oximeter.

C-42-91 (continued)

Progress: Study terminated. Principal investigator has department from  
Brooke Army Medical Center.

**Detail Summary Sheet**

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**Date:** 31 Dec 93                      **Protocol Number:** C-46-91                      **Status:** Terminated

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**Title:** Performance Predictor for the U.S. Army Practical Nurse Course (Licensed Vocational Nurse/LVN) and the National Council Licensure Examination-Practical Nurse (NCLEX-PN).

<b>Start date:</b> 9 Apr 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Sarah C. Shine, LTC, AN	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Nursing	<b>Associate Investigator(s):</b> Maryann G. Edmondson, CPT, AN Debra D. Mark, CPT, AN
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

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**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

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**Objective(s):** To examine the relationship between a variety of independent variables (TABE test scores, Phase I GPA, GT Scores, Phase II GPA) and a) success in the U.S. Army Practical Nurse Course (PNC), b) performance on the NCLEX-PN.

**Technical Approach:** A descriptive, retrospective method will be used to conduct the study of 206 male and female PNC students with an age range of 19 of 37 years.

**Progress:** Study terminated. Principal investigator has departed from Brooke Army Medical Center.

# Detail Summary Sheet

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**Date:** 31 Dec 93      **Protocol Number:** C-63-91      **Status:** Terminated

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**Title:** Organizational Communications Assessment of the Department of Nursing (DON), Brooke Army Medical Center.

<b>Start date:</b> 17 Jul 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Carol A. Reineck, LTC, AN	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Nursing	<b>Associate Investigator(s):</b> Hiluard G. Rogers, MAJ, MS Darryll E. Stafford, MAJ, MS
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

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**Objective(s):** To assess the BAMC DON organizational communication practices.

**Technical Approach:** The organizational communication assessment will focus on written and verbal communication generated by the senior staff member level within the Department of Nursing. Units of analysis will include the following: a) non-participant observation during routine staff decision and information meetings, b) rhetorical analysis of written documents, c) results of a communication questionnaire, d) results of the Myers-Briggs Type Inventory, and e) semi-structured interviews of a sample of newly assigned personnel.

**Progress:** Study terminated. Principal investigator has PCS'd from Brooke Army Medical Center.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-67-91 Status: Completed

Title: Comparison of Enlisted Personnel Who are Participating in the Stress Management Unit Program (SMU) with Those Who Have Not Participated in the Program.

Start date: 30 Jul 91	Estimated completion date: 30 Jul 92
Principal Investigator: Linda S. Hartsock, CPT, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100

Total number of subjects enrolled to date: 100

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To describe health locus of control, state and trait anxiety levels, self-esteem, personality characteristics, and stress/coping skills of enlisted personnel who are participating in the Stress Management Program compared to those who have not participated in the program.

Technical Approach: This descriptive study will explore the similarities and differences between those who use the Stress Management Program compared to those who do not on measures of: health locus of control, state and trait anxiety, personality characteristics, self esteem and stress management skills. Program will have a) lower self esteem, b) higher levels of state anxiety, and c) higher stress and more effective stress management skills than those who do not decide to participate in the program.

Progress: Data is being entered into the computer for analysis.

(Data collection phase has been completed). No complications with subjects completing the above questionnaires.

# Detail Summary Sheet

**Date:** 1 Dec 93      **Protocol Number:** C-93-35      **Status:** Ongoing

**Title:** A Comparison of Nurses' Knowledge of Alcoholism and the Care of the Alcoholic Patient

<b>Start date:</b> Dec 92	<b>Estimated completion date:</b> Apr 94
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<b>Principal Investigator:</b> Evelyn Swenson-Britt, M.S. RN	<b>Facility:</b> Med Cen Hosp, SA Brooke Army Medical Center, Texas
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<b>Department/Service:</b> Nursing	<b>Associate Investigator(s):</b> Gretchen Carrougher, MN, RN Jean M. Johnson, Ph.D.
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**Key Words:**

<b>Cumulative MEDCASE cost:</b> NA	<b>Estimated cumulative OMA cost:</b> NA
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**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** Total 80; 20 from BAMC  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To compare nurses' knowledge and demographic information, attitudes regarding alcoholism, cognitive understanding of the related pathophysiology, and knowledge of standards of medical and nursing care. A total of 100 nurses from four med/surg nursing units (25 per group) will be asked to participate. There will be no sex or age limitations for participation and both registered and licensed practical/vocational nurses will be included. A quasi-experimental research design, similar to the Solomon Four Group design will be utilized to determine if the educational intervention provided has an impact on nurses' knowledge of alcoholism and the care of the alcoholic patient.

**Technical Approach:** The hypothesis including description of subjects, inclusion/exclusion criteria, experimental design/methods, data collection and specifics included in protocol.

**Progress:** Data collection is completed. Data analysis in progress.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-124-89                      Status: Terminated

Title: To Compare the Effects of Continuous Versus Cyclic Continuous Estrogen-Progestin Therapy on Fasting Serum Lipoproteins in Postmenopausal Women.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator: Clifford C. Hayslip, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the effects of continuous versus cyclic hormonal replacement therapy on the fasting serum lipoprotein profiles (FLP) of post-menopausal women.

Technical Approach: One hundred postmenopausal patients routinely seen at the GYN clinic will be asked to participate in the study. Women who have been on cyclic ERT, women taking Premarin only, and women on no hormonal replacement will be the three study groups. Patients on cyclic ERT, will have baseline FLP drawn on days 1, 15 and 25 of the month. At this time these patients will be switched to continuous therapy, and their FLP rechecked after two months in continuous therapy. Patients on Premarin alone, and postmenopausal patients on no therapy will be asked to have a single baseline FLP performed prior to entering the study. At this time they will be placed on three months of cyclic therapy, followed by three months of continuous therapy. FLP will be performed on these patients in a similar manner on days 1, 15 and 25 of the third month of cyclic therapy, and at random a single time after two months of continuous therapy.

Progress: Study terminated. Principal investigator retired 9/92 and study not continued.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-64-90 Status: Completed

Title: The Effects of Magnesium Sulfate Tocolysis on Electrolytes and Hormones of Calcium Hemostasis.

Start date: 9 May 90	Estimated completion date:
Principal Investigator: Paul M. West, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s): Arthur S. Maslow, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 28  
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): 1) Establish in detail the extent of electrolyte and hormonal alterations caused by therapy with magnesium sulfate for the preterm labor versus the pre-eclamptic patient and their neonates. 2) Determine if such electrolyte and hormonal disturbances correlate with the type of intravenous fluids infused or concentration of magnesium sulfate given. 3) Demonstrate that despite probable statistically significant changes in some electrolytes and hormones, clinically significant events are extremely rare, in support of available anecdotal literature.

Technical Approach: This study will include 25-30 patients in preterm labor treated in the standard manner with magnesium sulfate. Urinary electrolytes, serum/urine osmolarity, PTH, calcitonin, and anion gap will be evaluated. The control group will include 5-10 pre-eclamptic patients as positive controls and 5-10 normal patients as negative controls.

Progress: Study completed without additional patients and presented at Armed Forces District, American College of Obstetricians and Gynecologists, Seattle, WA, Nov 93.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-15

Status: Terminated

Title: A Comparison of the Effects of Transdermal Estrogen Replacement Therapy Versus Oral Estrogen Replacement Therapy on Serum Lipids.

Start date: Feb 92	Estimated completion date:
Principal Investigator: CPT Susan R. Gaire, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): CPT Maria Perez-Montes, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 5  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if transdermal estrogen replacement produces cardioprotective changes in serum lipids. If so, that they are comparable to those changes produced by oral estrogen replacement in menopausal women.

Technical Approach: To prove that transdermal estrogen produces cardioprotective changes on serum lipids comparable to oral estrogen in menopausal females.

Progress: Principal investigator PCS'd and protocol was terminated.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-17                      Status: Terminated

Title: Postpartum Hypothyroidism: Prevalence, Symptomatology and Response to Treatment

Start date:	Estimated completion date:
Principal Investigator: CPT Jacqueline Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the prevalence of postpartum thyroid disease and to measure the associated symptomatology. Further, to determine in a prospective randomized fashion whether treatment of postpartum hypothyroidism decreases morbidity.

Technical Approach: Postpartum women of all races and ages who present to the Brooke Army Medical Center OB/GYN Clinic for their 6-8 week postpartum check will be asked to enter the study. Those women with a previous history of thyroid disease requiring treatment will be excluded.

Progress: Study terminated. Principal Investigator PCS'd July 1993.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-44

Status: Terminated

Title: Feasibility Study for the Fetal Heart Rate Monitor

Start date:	Estimated completion date:
Principal Investigator: COL Manuel C. Morales, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): Dean C. Winter, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the technology applied in a previous study to measure the heart rate of soldiers wearing heavy protective gear (ref 1) can be applied to non-invasively monitor fetal heart rate during various stages of labor.

Technical Approach: Health low-risk patients between the ages of 18-35, approved for the study by a BAMC physician. Although not essential to the study, the preference is to measure patients who have had a previous healthy delivery.

Progress: Study was never started because the Southwestern Research people moved it to another medical treatment facility.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-49

Status: Terminated

Title: A Prospective Randomized Study on the Efficacy of Oral Contraceptive Therapy in the Treatment of Ovarian Cysts

Start date:	Estimated completion date:
Principal Investigator: CPT Paul L. Jones, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): LTC Clifford C. Hayslip, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of oral contraceptive therapy in patients with simple ovarian cysts and the rate of resolution of ovarian cysts as measured by transvaginal ultrasound. To determine whether serum LH and FSH levels are predictive of the response to treatment.

Technical Approach: Sixty women with adnexal cysts measuring greater than or equal to 2.0cm mean diameter on transvaginal ultrasound will be randomized to treatment or control groups. The treatment group will be placed on ethinyl estradiol (35 mcg) and norethindrone (1 mg) for two cycles. Patients will be evaluated every week for 4 weeks and then every 2 weeks until the cyst has resolved.

Progress: Study terminated. Both investigators have PCS'd.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-14                      Status: Ongoing

Title: Determination of Excretion of Urinary Albumin, Calcium, and Total Protein in 24 Hour Urine Specimens from Healthy Pregnant Women by CPT John Phelps III

Start date: 4 Dec 92	Estimated completion date:
Principal Investigator: John Y. Phelps, III, M.D. & Ken Higby, M.D.	Facility: Univ of TX at SA Brooke Army Medical Center, Texas
Department/Service: Department Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	Manuel Morales, M.D. Mark Grant, M.D. Oded Langer, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 233

Total number of subjects enrolled to date: 235

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the excretion of albumin, calcium, and total protein in normal healthy pregnant women.

After the above is established, to test the following hypothesis: (1) Microalbuminuria is a predictor of the development of preeclampsia; (2) A low calcium/creatinine ratio in urine is a predictor of the development of preeclampsia.

Technical Approach: Preeclampsia is a common disorder of pregnancy and a major cause of maternal, fetal, and neonatal mortality and morbidity. Its prevention would have a major impact on perinatal morbidity and mortality. The signs and symptoms of the disease usually present in the third trimester. However, the pathophysiologic mechanisms involved are felt to begin much earlier in pregnancy (8-18 weeks of gestation). It thus seems prudent to search for early indicators of the disease.

Progress: Data collection has been completed but additional funds have been requested to continue this study. An abstract was submitted on 1 Sep 93. Paper to be presented by Dr. Hibgy at Society of Perinatal Obstetrics Meeting 24-29 Jan 94, Las Vegas, Nevada.

# Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-82 Status: Ongoing

Title: Simulation of Cervical Diameter Measurements: An Appraisal of Accuracy

Start date: 14 May 93	Estimated completion date: 1 Jan 94
Principal Investigator: John Y. Phelps, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s): Michael H. Smyth, M.D. Kenneth Higby, M.D. Allan R. Mayer, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 123  
Total number of subjects enrolled to date: 123  
Periodic review date: Review results:

Objective(s): To assess the accuracy of clinical cervical diameter measurements using cervical simulators, and to compare these results among attending obstetricians, residents of various year levels, and labor and delivery nurses. Methods and results included in protocol.

Technical Approach: Specifics outlined in protocol.

Progress: Data collection completed. Paper presented at Armed Forces District Meeting Nov 93. In process of rewriting paper to submit for publication.



Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-15-91 Status: Terminated

Title: Plasmacytoma of Appendix.

Start date: 30 Nov 90	Estimated completion date:
Principal Investigator: John P. Wohler, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pathology	Associate Investigator(s): Donald Shafer, MAJ, MC Nguyen H. Dich, LTC, MC Frank Robertson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To investigate retrospectively a single case to demonstrate the neoplastic nature of a proliferation of plasma cells within the appendix-caecum.

Technical Approach: This will be a descriptive study.

Progress: Study not pursued. Principal investigator PCSd from Brooke Army Medical Center.

### Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-20

Status: Terminated

Title: Pagetoid Intraepithelial Malignancy and In Situ Transitional Cell Carcinoma Involving the Residual Penile Urethra Following Cystoprostatectomy for High-Grade Transitional Cell Carcinoma of the Urinary Bladder.

Start date:	Estimated completion date:
Principal Investigator: LTC Michael H. Enghardt, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology	Associate Investigator(s): LTC Ian M. Thompson, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine via immunohistochemical procedures whether or not the pagetoid cells are of transitional cell origin and to explore possibilities of histogenesis of the pagetoid intraepithelial malignancy, specifically the possible relationship to the adjacent in situ transitional cell carcinoma and the preceding invasive transitional cell carcinoma of the bladder.

Technical Approach: It is to be determined whether or not Uro-9 and Uro-10 antibodies can be used with immunohistochemical systems applied to formalin-fixed paraffin-embedded tissues rather than frozen tissue. This shall be done with the avidin-biotin-peroxidase complex technique. The optimal conditions for consistent staining of fixed tissues need to be determined.

Progress: Project terminated because of unsuccessful immunostaining.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-13                      Status: Ongoing

Title: Islet Cell Hyperplasia of the Pancreas in Adults: An Immunohistochemical and Morphometric Study

Start date: 4 Dec 92	Estimated completion date: 4 Dec 94
Principal Investigator: Melton H. Fish, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology	Associate Investigator(s): M. H. Enghardt, M.D. J. I. Smith, M.D. K. J. Carlin, M.D. I. A. Chapa, MT E. Ayala, MA
Key Words: Islet cell hyperplasia, pancreas, nesidioblastosis, hyper insulinemia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period:     N/A      
 Total number of subjects enrolled to date:     N/A      
 Periodic review date:                      Review results:                     

Objective(s): To determine whether or not the pancreatic endocrine volume - measured as area of endocrine tissue and expressed as a percentage of total glandular area - in two BAMC cases of patients with hyperinsulinemic hypoglycemia differs significantly from the relative endocrine volume in pancreata for age- and sex-matched controls. In contradistinction to the studies which disclaim an increase of endocrine volume, we hypothesize that one is present in our cases.

It is necessary to address a thorough review of the world's literature in order to completely document experience with diagnosis and with both medical and surgical therapy of hyperinsulinemic hypoglycemia caused by nesidioblastosis/islet cell hyperplasia. Modes of therapy and their outcome from all reported cases in adults, including our own, will be tabulated and evaluated.

Technical Approach: Archival tissue from two patients. Control tissues from age and sex matched control pancreata obtained via South Texas Organ Bank. Animal studies not required.

Progress: Control tissues available. Cell imaging system set up. Morphometric studies to be done as the next step.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-17                      Status: Completed

Title: Becton Dickinson Microbiology Crystal Identification Systems

Start date: 10 Dec 92	Estimated completion date:
Principal Investigator: Betty Jeffery	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology & Area Labs	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100  
 Total number of subjects enrolled to date: 100  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To generate a comprehensive and accurate database, of biochemical and enzymatic reactions, for clinically relevant micro-organisms with Crystal Enteric/Non-fermenter Panels. To this effect, all test isolates should be well identified prior to testing in Crystal panels. Spot tests for Indole and Oxidase should be performed using the BD supplied reagents. All results should be recorded on the BD data sheets provided, and submitted to BDMS on a regular basis.

Technical Approach:

Progress: Reached final stated goal and results forwarded to Becton Dickinson.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-116      **Status:** Ongoing

**Title:** Development of a Synthetic Biologic Control for Immunohistochemical Procedures

<b>Start date:</b> Aug 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Michael H. Enghardt, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Pathology and Area Laboratories	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** Design and manufacture a semisynthetic tissue control using red cell membranes, latex granules and purified antigen.

**Technical Approach:** Pig blood will be used as the source of red cells. Blood may be collected from any pig that is on a terminal study and is a part of an approved animal use protocol. The blood will be collected while the animal is anesthetized, just prior to euthanasia. Further details in protocol.

**Progress:** Initial model system produced. Patent application pending.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-34-85                      Status: Terminated

Title: Effect of Dietary Modifications on Weight Change in Obese Children with Different Insulin Response to Glucose and Leucine Challenge.

Start date: 29 Apr 85	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Departments of Pediatrics	Associate Investigator(s): Juliann M. Walker, LT, MS
Key Words: Children, Obese	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5

Total number of subjects enrolled to date: 113

Periodic review date: 14 May 91      Review results: Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

2) To develop a profile for these children by identifying common characteristics according to their insulin responses to tolerance testing.

Technical Approach: Eligible patients will have a complete history, physical, CBC, SMAC-20, oral glucose tolerance test (1.75 gm/kg, max. 100 gms); and oral leucine tolerance test (150 mg/kg). Subjects will be classified into elevated and normal insulin groups in accordance with their insulin response to glucose and leucine challenges. All participants will receive dietary instructions and will be provided with behavior modification instructions.

Progress: No new data accrual. Principal investigator PCSd from Brooke Army Medical Center

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-79-87                      Status: Ongoing

Title: Appetite and Pectin.

Start date: 9 Sep 87	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Appetite Obesity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23

Total number of subjects enrolled to date: 131

Periodic review date: 14 May 91      Review results: Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: Principal investigator PCSd and study was not continued.

Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-24-88 Status: Ongoing

Title: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: James H. Brien, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: 66 (FY 90)  
Periodic review date: 25 May 91 Review results: Continue

Objective(s): To determine the effectiveness of ceftriaxone in the outpatient management of children three to thirty-six months of age with suspected occult bacteremia.

Technical Approach: Children are randomized to receive either ceftriaxone IM, Augmentin PO with ongoing follow-up until fever and illness is resolved.

Progress: Due to the principal investigator's reassignment to Walter Reed Army Medical Center, this project has had no patients enrolled since last review.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-90-88                      Status: Ongoing

Title: Phase I Study of Piritrexim in Children with Advanced Leukemia and Solid Tumors (A Multicenter Study under the Direction of Dr. Thomas E. Williams, Santa Rosa Childrens Hospital).

Start date: 22 Nov 88	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words: Leukemia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To define the maximum tolerated dose and the dose limiting toxicity when Piritrexim capsules are administered orally to children in a daily x 5 schedule repeated every three weeks.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No reportable information available.

# **Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-37-90                      **Status:** Ongoing

**Title:** The Incidence of Congenital Respiratory Syncytial Virus.

<b>Start date:</b> 12 Mar 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> LTC Howard S. Heiman, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b> MAJ Thomas Perkins, MC CPT Michael Battista, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** A prospective study to determine if respiratory syncytial virus can be transmitted congenitally, and the incidence of RSV in the newborn population. Study population will include all women who deliver at Brooke Army Medical Center and their newborns, both term and premature.

**Technical Approach:** All newborns will receive routine DeLee suctioning of oral and nasopharynx on the perineum or abdomen by obstetrics. The specimen will be sent to the area lab for RSV ELISA. On all newborns who are RSV ELISA positive acute and convalescent serum titers for RSV will be obtained.

**Progress:** No patients entered because of change in personnel. We are currently reorganizing our efforts to institute the protocol.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-62-90                      Status: Ongoing

Title: High-Dose Chemotherapy with Autologous Bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Medical Center).

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Allan R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Glenn Edwards, MAJ, MC, WRAMC David Maybee, COL, MC, WRAMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 20 May 90      Review results: Continue

Objective(s): 1) To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors.

2) To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

Technical Approach: To be eligible for this study, patients must be < 21 years of age, have an estimated survival of at least 8 weeks, and have adequate blood counts prior to bone marrow harvest. Therapy will follow the schema outlined in the study protocol.

Progress: Study still continuing. No reportable data as of this date.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-32-91 Status: Ongoing

Title: Evaluation of Cisapride (R 51,619) in Patients with Gastrointestinal Motility Disorders.

Start date: 20 Feb 91	Estimated completion date:
Principal Investigator: Judith O'Connor	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of cisapride on the symptoms of unexplained upper abdominal pain, nausea, vomiting, anorexia, early satiety, bloating/distension in patients with gastrointestinal motility disorders.

Technical Approach: The patient will receive cisapride tablets or suspension 50 mg tid for six weeks. If improvement is observed, the patient may continue to receive cisapride on a long-term basis for up to 48 months.

Progress: Study still open. No reportable data as of this date.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-2 Status: Ongoing

Title: Childhood Obesity: Incidence Density Among Childhood Military Dependents and Association of Obesity with the Duty Status of the Sponsor

Start date: Feb 92	Estimated completion date:
Principal Investigator: COL Chandra Tiwary, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Childhood Obesity Incidence, Duty Status	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 500  
 Total number of subjects enrolled to date: 500  
 Periodic review date: Review results:

Objective(s): To describe the incidence density of childhood obesity among the dependents of US Army personnel. The association between incidence of obesity and the active duty or retiree status of the sponsor will also be assessed.

Technical Approach: All children beyond the age of 1 year attending the pediatric and adolescent clinic of the Brooke Army Medical Center will be included in this study. Their order of birth, name, gender, date of birth/age, height, weight, the sponsor's social security number, rank, duty status (active duty or retired), year when retired from the military, age on retirement and the current age will be recorded.

Progress: Currently collating and analyzing data. Help of a data entry clerk is needed.

**Detail Summary Sheet**

**Date:** 31 Dec 93                      **Protocol Number:** C-92-82                      **Status:** Ongoing

**Title:** Blood Lead (Pb) Levels in Infants and Toddlers

<b>Start date:</b> Sep 92	<b>Estimated completion date:</b> '94
<b>Principal Investigator:</b> CPT Deborah Baumann, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Pediatrics	<b>Associate Investigator(s):</b> LTC Allan Potter, MC Gea Miller, M.D. COL John D. Roscelli, MC
<b>Key Words:</b> Lead	
<b>Cumulative MEDCASE cost:</b> No additional funds	<b>Estimated cumulative OMA cost:</b> No additional funds

**Number of subjects enrolled during reporting period:** 810  
**Total number of subjects enrolled to date:** 1142  
**Periodic review date:** 22 Mar 93                      **Review results:** \_\_\_\_\_

**Objective(s):** To ascertain the incidence of lead exposure in the military dependents attending 6, 12, and 24 month well baby clinics. We will screen the children with a 5-part questionnaire. Any 6-month old infant found to be at risk for Pb exposure based on answers to their questionnaire will receive a blood lead level. All 12 and 24 month old children will receive a blood lead level in combination with a questionnaire. The infants will receive followup care at Brooke Army Medical Center (BAMC) based on blood lead results to include: education on sources of Pb exposure, environmental evaluations, dietary modification, medical evaluations, and chelation therapy if needed.

**Technical Approach:** We propose a descriptive study to investigate the incidence of lead exposure in military dependents.

**Progress:** Blood samples collected from 420 12-month old and 390 6-month old children. Data still being collected. Complete report of results of study are not available as of this date.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-09                      Status: Ongoing

Title: Extracellular Fluid Volume Loading and Prevention of Amphotericin B Nephrotoxicity

Start date: 19 Oct 92	Estimated completion date:
Principal Investigator: Luisa Gomez, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): John Roscelli, M.D. Theodore Cieslak, M.D. Martin Weise, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19  
 Total number of subjects enrolled to date: 19  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To study the effects of acute extravascular fluid volume expansion at the time at the time of Amphotericin B administration on the prevention of Amphotericin B induced nephrotoxicity in patients less than 23 years of age. The study will be randomized, nonblinded and prospective.

Technical Approach: All pediatric patients <23 years of age who require Amphotericin B for suspected or proven deep mycosis will be eligible for the study. Patients excluded from the study will include those with known cardiac disease and those with significant renal disease - specifically a creatinine clearance of <50 ml/min per 1.73 m<sup>2</sup>. Calculated sample size for statistical significance is based on having an 80% chance of detecting an 80% reduction in the previously described 80% incidence of azotemia in the control group. This will require a sample size of 20 patients including 10 patients in the control group and 10 patients in the study group.

Progress: Still collecting patients/data.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-61      **Status:** Ongoing

**Title:** Low-Volume vs High-Volume Blood Culture Sampling in Immunocompromised Children

<b>Start date:</b> 23 Dec 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Theodore J. Cieslak, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** It has previously been suggested that low-volume blood culture sampling is adequate to detect most cases of bacteremia in children. Recent studies, however, demonstrate that large proportion of sepsis in immunocompromised children involves low microbial colony counts. This study will prospectively seek to determine whether high-volume blood sampling for culture will significantly improve the ability to detect bacteremia in this group of children.

**Technical Approach:** Specifics outlined in protocol.

**Progress:** This was designed to be a muti-center study. We have experienced technical difficulties in getting started. Study remains open for future enrollment.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-121                      Status: Ongoing

Title: Exogenous Surfactant Therapy in Premature Infants: A Multicenter Trial

Start date: 21 Jun 93	Estimated completion date:
Principal Investigator: Howard S. Heiman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Deborah J. Leander, R.N. Joanna C. Beachy Barbara S. Turner William Dean Glover
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The leading cause of death for prematurely born infants born in the US is Respiratory Distress Syndrome (RDS). Specific aims of this study are to incorporate findings from the current study and extend knowledge on exogenous surfactant types of exogenous surfactant (Exosurf & Survanta), three methods of administration (Sideport adapter, feeding tube, and double lumen endotracheal tube) and the resulting neonatal physiologic responses and outcomes. Secondary aim will be to determine the relationships between type of surfactant and administration technique, nursing assessed neonatal clinical cues of a hemodynamically significant patent ductus arteriosus, and neonatal outcomes.

Technical Approach: Hypothesis, synopsis, nursing/medical applications, status, study plan, and specifics outlined in protocol.

Progress: Waiting for nurse and equipment to come in.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-123      Status: Ongoing

Title: WAIS-R/WAIS-III Clinical Pilot Comparison

Start date: Jun 93	Estimated completion date: Dec 94
Principal Investigator: Pamelia Clement, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Psychiatry	Associate Investigator(s):
Key Words: Head Injury	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: Not yet reviewed

Objective(s): To determine if head injured subjects who are administered WAIS-R respond to selected WAIS-III clinical pilot items in a corresponding manner.

Technical Approach: Approximately 30 subjects will be required, consisting of individuals diagnosed within the criteria listed below:

Progress: Not yet reviewed.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-12-77                      Status: Ongoing

Title: Intravenous Administration of I<sup>131</sup> (NP59) for Adrenal Evaluation of Imaging.

Start date: 15 Nov 76	Estimated completion date:
Principal Investigator: Gilbert Sostre, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words: Adrenal Scan	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 11  
 Periodic review date: 16 Sep 92    Review results: Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1 mCi in adults and 15 Ci/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on the 4th, 7th, and 11th day following injection using scintillation camera.

Progress: There have been no new patients enrolled since 16 September 1992. Status is unchanged. Principal Investigator has PCS'd from BAMC. Request study remain open for patient accrual.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-47-89 Status: Ongoing

Title: Evaluation of <sup>131</sup>I-miBG (<sup>131</sup>I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia.

Start date: 20 Mar 89	Estimated completion date:
Principal Investigator: James D. Heironimus, LTC, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 40  
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To evaluate the use of <sup>131</sup>I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

Technical Approach: Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by <sup>131</sup>I-miBG scintigraphy.

Progress: This agent is proving to be accurate in the diagnosis of pheochromocytoma and neuroblastoma, though sensitivity in the latter is uncertain due to lack of positive cases. This study will be continued to provide this diagnostic tool. Principal Investigator has PCS'd from BAMC and study is continued by Associate Investigator.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-108-89 Status: Ongoing

Title: Evaluation of Interstitial Lymphoscintigraphy with Radioactive Technetium Antimony Trisulfide Colloid (99m Tc-Sb<sub>2</sub>S<sub>3</sub> for Lymphedema, Internal Mammary and Excised Malignant Melanoma Lymphoscintigraphy

Start date: 8 Sep 89

Estimated completion date:

Principal Investigator:  
James D. Heironimus, Lt COL, USAF, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Radiology

Associate Investigator(s):  
Neil Katz, MAJ, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 9  
Periodic review date: 16 Sep 92 Review results: Continue

Objective(s): To determine the effectiveness of radioactive Tc99m Antimony Trisulfide Colloid in imaging lymph nodes.

Technical Approach: Patients will be selected and referred to Nuclear Medicine Service primarily by the Surgery and Oncology Clinic. For evaluation for lymphedema, intradermal injections of the radiopharmaceutical will be made in the distal extremities of interest. To evaluate the lymph drainage paths of a dermal region, injections will be made intradermally immediately adjacent to the site of the skin lesion/biopsy site. For all studies, scintigraphic imaging will be performed using an Anger Gamma Camera system. Multiple use of the appropriate areas will be attained immediately following the injection of the radiopharmaceutical as well as approximately 1-4 hours after injection. Body outlining and/or flood field imaging techniques will be performed to provide additional positional information.

Progress: Since 16 Sep 92, one patient has been enrolled. Currently, agent is not available, though it is expected to be available in the future.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-19-91                      Status: Completed

Title: Changes in Hepatocyte Function Measured by Technetium TC-99M Mebrofenin.

Start date: 14 Jan 91	Estimated completion date:
Principal Investigator: Neil Katz, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): M. Oyewole Toney, LTC, MC Allan Parker, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 45  
 Total number of subjects enrolled to date: 45  
 Periodic review date:                      Review results:                     

Objective(s): To examine the prognostic and diagnostic role of radiopharmaceutical imaging to determine changes in hepatocyte blood flow and function over time in patients with document liver disease.

Technical Approach: Patients will undergo hepatobiliary scanning using 4-8 mCi Techetium TC-99m mebrofenin, a radiopharmaceutical currently used for hepatobiliary scanning for the assessment of acute cholecystitis. Time activity curves, which graphically depict radiopharmaceutical uptake and excretion will be generated for the imaging period of one hour.

Progress: Study results completed and presented in an abstract. One article is currently being written.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-26-91                      Status: Completed

Title: Evaluation of Bone Density Measurement of Young Adults with and without Stress Fractures.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Rhonda W. Wyatt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): M. Oyewole Toney, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 62  
 Total number of subjects enrolled to date: 62  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if bone density measurements correlate with presence of stress fractures.

Technical Approach: Bone scans are performed to determine if the patients has a stress fracture of the lower extremities and pelvis. The bone mineral density of each patient's lumbar spine, proximal femur, and forearm are obtained using dual photon absorbtometry. The bone mineral density (BMD) of patients without stress fractures is then compared with the BMD of patients with stress fractures.

Progress: Study closed. Principal Investigator has PCS'd from Brooke Army Medical Center.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-10                      Status: Completed

Title: The Effects of Oral Glucose Solutions on Gastric Emptying

Start date:	Estimated completion date:
Principal Investigator: LTC M. Oyewole Toney, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology/Nuclear Medicine	Associate Investigator(s): MAJ Neil Katz, MC
Key Words: Gastric Emptying Glucose Solutions	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: 14 Jan 94      Review results: Closed-30 Jun 93

Objective(s): To determine the role of a new hyperosmolar glucose solution in studying gastric emptying, and to determine initial normal values for our institution.

Technical Approach: Preliminary study would compare gastric emptying rates using our standard solid and liquid agents (eggs, and water, respectively), as well as a hyperosmolar glucose solution developed by Phillips, et al.

Progress: Study closed to patient accrual. Data being used internally.



# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-89                      Status: Completed

Title: Comparison of Film Screen Radiography, Computed Radiography, and Kodak Insight Filmscreen in Demonstrating Mediastinal Anatomy

Start date: 5 Oct 92	Estimated completion date: 27 Jun 93
Principal Investigator: CPT Timothy J. Cramer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Radiology	Associate Investigator(s): COL Anna K. Chacko, MC COL Michael D. Redwine, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 170  
 Total number of subjects enrolled to date: 170  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of conventional film screen radiography with computed radiography and the Kodak Insight Screen/film system in the evaluation of mediastinal anatomy and definition of five mediastinal lines in adult patients. The anatomic lines and stripes to be evaluated include the right paratracheal stripe, the right esophagopleural strips, the left paraspinal line, the right paraspinal line, and the aorticopulmonary stripe.

Technical Approach: Study will compare the ability of three radiographic methods to demonstrate mediastinal anatomy.

Progress: Data collection and preliminary statistical analysis are complete. The study has been accepted for presentation as a Scientific Paper at the American Roentgen Ray Society Annual Meeting, 24-29 April 1994. An invitation to publish has been made and final analysis, revision, and submission are pending.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-07                      Status: Terminated

Title: A Cohort Study of Bone Marrow MR Imaging following Pediatric Bone Marrow Transplantation

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: Thomas M. Anderson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology	Associate Investigator(s): Billy E. Cunningham, M.D. Michael D. Redwine, M.D. Allen Potter, M.D. Terry Pick, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3

Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the bone marrow in children with cancer returns to normal following high dose chemotherapy and bone marrow transplantation. The study population will include children 6 years of age or older receiving bone marrow transplants at BAMC during the time of this study. MR imaging of the bone marrow will be done prior to and at selected intervals following bone marrow transplants. There is no radiation exposure when using MR imaging, and there are no other risks to the patient.

Technical Approach: Proposed as a descriptive study that will describe MR findings in children who receive bone marrow transplants. We will compare the laboratory data, bone marrow biopsy and MR signal intensity of marrow to see if they correlate. The signal intensity of the marrow is calculated by the MR unit computer and not determined by the radiologist. Therefore, no bias is introduced by the radiologist into the statistical analysis of data.

Progress: Study terminated. Inadequate number of patients.

Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-30 Status: Terminated

Title: Definition and Differential Diagnosis of Increased Bronchovascular Markings

Start date: 19 Oct 92	Estimated completion date:
Principal Investigator: Timothy J. Cramer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology	Associate Investigator(s): R. B. Shah, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 150  
Total number of subjects enrolled to date: 150  
Periodic review date: Review results:

Objective(s): To demonstrate a correlation between a history of cigarette smoking, acute bronchitis, chronic bronchitis, and inhalation exposure with the radiographic manifestations early interstitial change.

Technical Approach: Routine PA and lateral chest radiographs submitted to the Department of Radiology for interpretation will be evaluated for the presence of findings of dirty lung. A total of 200 patients demonstrating these findings will be mailed or given questionnaires concerning their symptoms, smoking, and exposure history. Initial contact will emphasize that patient's chest radiograph was abnormal and all findings were appropriately discussed with the patient by the requesting physician. It will further be explained the purpose of this study is to investigate for early changes in the associated diseases. Questionnaires will be sent to those patients who agree to participate in the study. Those with previously diagnosed chronic bronchitis, emphysema, or any other radiographic abnormalities (such as nodules or adenopathy) will be excluded from the study.

Progress: After enrolling 150 patients, data analysis failed to reveal any significant trends to lead to proving the differential diagnoses proposed were correct. Additional information provided by recent publications and texts also

C-93-30 (continued)

point to multiple causes for increased bronchovascular markings on high resolution CT. These abnormalities were found in patients who were asymptomatic, and, with close epidemiologic investigation, no etiologies were proven.

Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-85 Status: Ongoing

Title: Efficacy of the Lateral Chest Radiograph on Computed Radiography Systems

Start date: Jul 93	Estimated completion date: Jul 94
Principal Investigator: Timothy J. Cramer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology	Associate Investigator(s): Anna K. Chacko, M.D. Joseph P. Spirnak, M.D. Raoul O. Hagen, M.D. Al Gest, M.D. James M. Lamiell, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the efficacy of the lateral chest radiograph on routine outpatients using computed radiography systems.

Technical Approach: This is a prospective study of 3000 PA and Lateral chest radiographs obtained on the CR system. Patients will be from the Emergency Dept and Acute Care Clinic. No patients will be excluded.

Progress: PA and lateral radiographs of 500 patients have been evaluated. No statistical correlation has been performed. Additional exams have been collected for evaluation, but have not been interpreted by two radiologists.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-50-87                      Status: Completed

Title: Chromosomal Analysis of Genitourinary Neoplasms.

Start date: 11 May 87	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Eric J. Zeidman, MAJ, MC Kurt L. Hansberry, CPT, MC Isidoro Chapa GS-7
Key Words: Karyotype	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$20,726.31

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: n/a                      Review results: \_\_\_\_\_

Objective(s): To correlate tumor karyotypes with patient data, tumor stage and grade, and clinical course of the disease.

Technical Approach: At the time of removal of a genitourinary tumor, a small piece of tumor tissue: is sent for karyotyping. The technique for karyotyping The technique for karyotyping employs the coverslip method. Chromosomal banding includes standard techniques for G-banding, Q-banding (fluorescence), and C-banding. Photographs include intact banded metaphase plates. Karyotyping will be according to standard nomenclature.

Progress: Study has been closed. Data currently being correlated.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-90-87 Status: Completed

Title: Opti-Fix™ Hip Prosthesis (Multicenter Study).

Start date: 21 Sep 87	Estimated completion date:
Principal Investigator: Allen L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Orthopedics	Associate Investigator(s):
Key Words: Prosthesis, hip	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 10  
 Periodic review date: 21 Oct 91 Review results: Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biologic fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: Patients requiring total hip replacement will be asked to participate in this study. If they agree, the Opti-Fix™ will be implanted as outlined in the study protocol.

Progress: This project was completed in November of 1992 when all 10 subjects completed a 5-year analysis utilizing the modified Harris Hip score and clinical radiographs. Average H.H.S. was 94 points. The rate of thigh pain was 0%. No loosening (radiographic) and no clinical failures are reported. The BAMC data correlates well with the overall national study which demonstrates a 2% thigh pain rate, no acetabular revisions, and a 2% femoral stem revision rate. The conclusions, based upon a total cohort group of 542 subjects, is that uncemented total hip replacement utilizing porous titanium implants is a safe and effective procedure for at least 5 years in properly selected patients with severe arthritis of the hip.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-79-88 Status: Ongoing

Title: Collaborative Ocular Melanoma Study.

Start date: 8 Sep 88	Estimated completion date: 1998
Principal Investigator: Donald A. Hollsten, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): William L. White, MAJ, MC
Key Words: Melanoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 2  
 Periodic review date: 16 Sep 91 Review results: Continue

- Objective(s): 1) To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas.
- 2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas.
- 3) To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

Technical Approach: Unchanged. Collaborative Ocular Melanoma Study is designed to determine the most effective way to treat choroidal melanomas. Patients are divided into small tumors, medium tumors and large tumors based on diameter and thickness of the melanoma. Individuals in the small category are observed while individuals in the medium category are randomly divided into two treatment groups. One group was enucleated and the second will have radiation plaque therapy applied to the melanoma. Individuals in the large melanoma group are divided into either enucleation with preoperative radiation or enucleation without preoperative radiation.

Progress: Brooke Army Medical Center is a single sub-center out of dozens



C-79-88 (continued)

around the country and our role will not be to collate, digest and evaluate the data but rather to provide patients to the central study authority at Johns

Hopkins University so that the appropriate number of cases can be entered into the study to achieve meaningful results. The first patient who was enrolled through Brooke Army Medical Center into the Collaborative Ocular Melanoma study has died from metastatic disease to his liver.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-2-89                      Status: Terminated

Title: Incidence of Asymptomatic Varicocele in Fertile Man

Start date: 22 Nov 89	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Eric J. Zeidman, LTC, MC Edmund Sabanegh, MAJ, MC (USAF) Edmund Sabanegh, MAJ, MC Francisco R. Rodríguez, COL, MC
Key Words: Varicocele	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: n/a Review results: \_\_\_\_\_

Objective(s): To determine the incidence of asymptomatic varicocele in a group of men with proven fertility.

Technical Approach: All men requesting bilateral scrotal vas ligation for contraception will be eligible for inclusion. Patient will undergo vasectomy in a routine fashion. Prior to vasectomy, Doppler examination will be performed of the left and right spermatic cords. Patients will be first examined recumbent during comfortable respirations. Then they will be asked to perform a valsalva maneuver, and if a venous whir is detected, will be designated as possessing varicocele by this test. Following venous Doppler, scrotal ultrasound will be performed. If, on valsalva, scrotal ultrasound detects veins within the spermatic cord of 3 mm or greater, a ultrasound-detected varicocele will be scored. Immediately prior to vasectomy, standard semen analysis will be performed to quantitate semen motility, morphology, and total count.

Progress: This study has been terminated due to the PCS of Dr. Sabanegh. After his return from an infertility fellowship, it may be re-initiated. of vasectomy patients will provide an easier method for patients counseling and for protocol completion.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-115-89                      Status: Ongoing

Title: Treatment of Metastatic Renal Cell Carcinoma with Cimetidine: A Phase II Trial.

Start date: 8 Sep 89	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Arlene J. Zaloznik, LTC, MC M. Ernest Marshall, M.D.
Key Words:	
Accumulative MEDCASE Cost:	Estimated Accumulative OMA Cost:

Number of subjects enrolled during reporting period:   1    
Total number of subjects enrolled to date:   4    
Periodic review date: 16 Sep 91    Review results: Continue

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further studies.

2) To evaluate and qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: All patients will receive cimetidine, 400 mg orally four times daily. There will be no dose reduction or escalation within this trial. Patients experiencing significant CNS toxicity will be removed from study. Any other toxicities requiring cessation of therapy will be documented.

Progress: No further patients have been accrued. The one patient remains NED.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-127-89 Status: Terminated

Title: A Randomized Prospective Study of Lumbar Spinal Fusions with and without Transpedicular Screw-Plate Fixation.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator: Jeffrey D. Coe, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Orthopedic	Associate Investigator(s): William C. Lauerma, MAJ, USAF, MC James E. Cain, MAJ, USAF, MC Kevin P. Murphy, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 18  
 Periodic review date: 10 Sep 90 Review results: Continue

Objective(s): To compare the results of spinal fusion with and without the use of transpedicular instrumentation in the lumbar spine.

Technical Approach: In a multi-center study to be performed by the Orthopaedic Surgery Services of the Joint Military Medical Commander of San Antonio, a randomized prospective study will be performed in patients undergoing lumbar spinal fusions. The study group will undergo transpedicular instrumentation with Steffee (VSP) bone plates and screws and the control group will undergo fusion without instrumentation. A total of 100 patients will be entered into the study (approximately 30 to 40 at BAMC). The primary goal of the study is to determine if there is a difference in subjective pain relief, fusion rates, and complication rates between the study group (instrumented and fused) and the control group (instrumented and fused).

Progress: Study is terminated. All investigators, primary and secondary, have completed obligated military service without providing data. Currently, of the 18 enrolled subjects, no clinical failures have been identified. The proposed surgical techniques remains the standard of care, based upon surgeon's preference, and no national data exists to support one technique over the other.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-8-90 Status: Completed

Title: Clinical Evaluation of Collagen/Chlorhexidine (VitaPatch) Surgical Dressing and Traction Pin Badge.

Start date: 7 Dec 89	Estimated completion date:
Principal Investigator: Allan L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Orthopaedic	Associate Investigator(s): Daryl W. Peterson, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50  
Total number of subjects enrolled to date: 50  
Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To evaluate the safety and effectiveness of a new pin protection device called VitaPatch™. The effectiveness of VitaPatch will be evaluated in terms of differences in the rate of bacterial colonization/infection, site appearance, convenience of use, and patient comfort as compared with established protocol.

Technical Approach: All patients over the age of 18 who have fresh fractures treated with external fixation devices will be eligible for the study. Prospective patients are evaluated at the request of the primary physician, and a determination for inclusion made by the primary investigators. Each patient will serve as his/her own control with the same number of pins used as controls as the number of pins testing VitaPatch. Control VitaPatch test pins are to be alternated so that no bias is introduced.

Progress: Results of data analysis is not yet finalized. We anticipate completion in the near future.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-32-90                      Status: Completed

Title: Intravenous Injection of Prostaglandin E1 for Erectile Impotency.

Start date: 13 Feb 90	Estimated completion date:
Principal Investigator: Ramón L. Caballero, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Urology Service	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words: Impotency, Erectile	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 17  
 Total number of subjects enrolled to date: 18  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): To determine the benefit of intravenous penile injection of prostaglandin E1 in patients with erectile impotency.

Technical Approach: Patients will complete a questionnaire, undergo a full genital exam and battery of blood tests at the beginning of the study, Part 1 of the study will involve in office, physician supervised injections into the penile bodies at weekly intervals until an adequate dose is reached not exceeding a maximum predetermined dose. Part 2 will involve home self-injections in patients who are successful in phase 1.

Progress: This study is now complete. PEG1 is now being offered for outpatient treatment of impotence.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-53-90                      Status: Terminated

Title: A Comparison of Arterial Oxygen Partial Pressure Achieved with Intermittent Flow Oxygen (IF) from Demand Controller and Continuous Flow Oxygen (CF).

Start date: 3 Apr 89	Estimated completion date:
Principal Investigator: Charles P. Kingsley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Anesthesiology	Associate Investigator(s): Joseph P. Ducey, MAJ, MC William Strong, CPT, MC Linda Strezlecki, LTC, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 16  
 Periodic review date: 20 May 91 Review results: \_\_\_\_\_

Objective(s): Animal studies and human studies in chronically ill patients have shown that intermittent flow oxygen delivered by a demand oxygen controller (DOC) maintains arterial oxygen tensions at values that are equal to those values with continuous flow oxygen (CF). Twenty five postoperative patients for pulmonary surgery will be studied in a randomized crossover design.

Technical Approach: Twenty five adult patients schedule for pulmonary surgery requiring routine arterial catheter placement and postoperative intensive care admission will be enrolled in the study. A randomized crossover design with each patient serving as his own control will be employed to evaluate the arterial oxygen partial pressures achieved with intermittent oxygen therapy from a demand oxygen controller compared to continuous flow oxygen at comparable flow rates. Arterial blood gases will be draw at 30 minute intervals, and total oxygen use will be recorded. Continuous pulse oximetry will insure adequate oxygen delivery.

Progress: Study terminated. Principal investigator ETS'd before final data results were available.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-61-90 Status: Ongoing

Title: Swimming and Myringotomy Tubes.

Start date: 12 May 90	Estimated completion date:
Principal Investigator: Kweon I. Stambaugh, LTC, MC	Facility: Brooke Army Medical Center
Department/Service: Department Surgery/Otorhinolaryngology	Associate Investigator(s): Jeffrey Braaten, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100  
 Total number of subjects enrolled to date: 160  
 Periodic review date: Oct 92 Review results: Continue

Objective(s): To determine the incidence of ear infection while swimming with middle ear ventilation tubes.

Technical Approach: All patients undergoing myringotomy and insertion of ventilation tubes that are intact and patent during the swimming season, June thru September, will be included in the study. Swimmers and non-swimmers will be randomized by a table of random numbers. A variety of ventilation tubes will be placed based on the surgeons personal preference. Patients will be seen routinely two weeks postoperatively and then every three months thereafter until the tubes are extruded. Patients will be given a calendar and questionnaire. The days swimming, the number of ear infections, and their relationship to an upper respiratory infection will be recorded.

Progress: Study ongoing for patient accrual and data analysis.



# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-91-90 Status: Ongoing

Title: The Incidence of Prostatism in Older Males Presenting for Herniorrhaphy.

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Kevin Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 78  
 Total number of subjects enrolled to date: 78  
 Periodic review date: Review results:

Objective(s): To determine the incidence of prostatism in males 40 years of age and older who present for herniorrhaphy.

Technical Approach: One hundred consecutive men scheduled for herniorrhaphy will undergo urodynamics evaluation in an attempt to detect asymptomatic or minimally symptomatic physiologically-significant bladder outlet obstruction secondary to prostatic hyperplasia. Should such obstruction be encountered, Urology consultation would be requested before herniorrhaphy is undertaken.

Progress: Study complete. Male patients presenting for herniorrhaphy and are >40 y.o. should be evaluated for BPH.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-95-90 Status: Ongoing

Title: Effect of the Use of Perioperative Antibiotics in the Incidence of Wound Infection Following Mastectomy.

Start date: 1 Aug 89	Estimated completion date:
Principal Investigator: Steven B. Olsen, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/General Surgery	Associate Investigator(s): Daniel P. Otchy, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 31  
 Total number of subjects enrolled to date: 38  
 Periodic review date: Review results: Continue

Objective(s): To prospectively analyze the effect of perioperative antibiotic use on the incidence of wound infection following mastectomy.

Technical Approach: This subject population will include all females who present to the General Surgery Service from August 1989 to December 1990. The subjects will be randomized to one of two double-blinded groups: the first group will received intravenous antibiotics in a standard perioperative regimen consisting of a dose preoperatively and postoperative doses for 24 hours postoperatively, and the second group will receive intravenous doses of saline at the same times when antibiotic would normally be administered. The incidence of wound infections and other infective complications will be monitored during the hospital stay and at follow-up visits.

Progress: Status is uncertain. Principal investigator did not provide us with a report.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-98-90                      Status: Ongoing

Title: An Open Label Extension Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension.

Start date: 7 Sep 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Julius L. Teague, LTC, MC Leonard G. Renfer, MAJ, MC Douglas A. Schow, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 19 Nov 92      Review results: Continue

Objective(s): 1) To determine the long-term safety and efficacy of doxazosin tablets in hypertensive patients with benign prostatic hyperplasia (BPH).  
 2) To obtain information regarding the optimal dose of doxazosin tablets required on a long-term basis for patients with BPH.

Technical Approach: Patients who successfully complete the 16 week (double blind study may enter the open label extension study. They must do so within one week. Patients who withdrew from the 16 week study, after randomization, due to adverse experiences or lack of efficacy may also enter. The study is designated as an open-label, long-term, follow-up trial to the initial 16 week study. All patients in the open label trial will initially receive 1 mg of doxazosin daily and will be titrated upward at two week intervals, one dose level at a time, to a daily dose of 2, 4, 8, or 12 mg. A patient's upward titration will be dependent upon their adverse experiences, blood pressure response and BPH symptomatology. Once an optimal dose is achieved, it will be maintained unless the investigator determines that an adjustment in dose (lower or higher) is medically indicated.

Progress: This study extends on an open-label basis the use of doxazosin to previously randomized patients on the 16-week placebo-controlled dose-response study with this agent. To date, six patients have enrolled, four patients are experiencing benefits of this agent and two dropped due to lack of efficacy

C-98-90 (continued)

and one due to worsening of urinary symptoms. All patients with acceptable blood pressure and urinary symptom improvement with this agent will be kept at the dose achieved and periodically re-evaluated for patient satisfaction and blood pressure control. Enrollment is closed.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-1-91                      Status: Completed

Title: Use of a Foot compression Pump in the Prevention of Deep Vein Thrombosis in Total Joint Replacement.

Start date: 8 Nov 89	Estimated completion date:
Principal Investigator: James P. Stannard, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): Robert M. Harris, CPT, MC Jeffrey J. Behrens, MAJ, MC Allan L. Bucknell, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 150  
 Periodic review date: Dec 92                      Review results: \_\_\_\_\_

Objective(s): To determine the clinical usefulness of the AVI foot pump as prophylaxis for DVTs.

Technical Approach: Subjects for this study will be patients undergoing either hip replacement arthroplasty or total knee replacement arthroplasty. Patients will be randomized into one of three groups. Group A will be patients given subcutaneous heparin for the first 3 days (or until ambulatory) and then given Ecotrin as prophylaxis for DVTs. Group B will be patients given an AVI foot pump as their prophylaxis. The pump will be used at all times when the patient is in bed or in a chair. Group C will be patients given both the Heparin/Ecotrin regimen and a AVI foot pump. All patients will be evaluated for the development of DVTs via serial Duplex ultrasound screening at weekly intervals while the inpatients.

Progress: Protocol not currently being investigated. Study completed in Dec 92.

40/75 hips enrolled with no deep vein thromboses (vs. 4 in controls) and more rapid wound closure with foot pump.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-7-91 Status: Completed

Title: Prognostic Value of Static DNA Cytophotometry for Stage A1 Adenocarcinoma of the Prostrate.

Start date: 30 Sep 90

Estimated completion date:

Principal Investigator:  
David Bomalaski, CPT, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Surgery/Urology

Associate Investigator(s):  
Wilfred Kearse, CPT, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if nuclear DNA content, as determined by static DNA cytomorphometry, has any prognostic value in predicting progression of disease or survival.

Technical Approach: Follow-up data on 56 patients with stage A1 adenocarcinoma the prostate has been accumulated. Paraffin embedded tissue specimens have been reviewed and the blocks chosen that contain cancer. They propose to Feulgen stain these specimens and perform static DNA analysis on these specimens. The ploidy the specimens will be compared to the clinical outcome to asses prognostic significance.

Progress: Study has been closed. Data being analyzed.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-20-91                      Status: Terminated

Title: Use of a Foot Pump on Reduction of Postoperative Pain and Swelling in Lower Extremity Injuries Requiring External Fixation.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Robert M. Harris, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): James P. Stannard, CPT, MC Steve Martin, CPT, MC Allan L. Bucknell, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
 Total number of subjects enrolled to date: 23  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the clinical effectiveness of the AVI Foot Pump in the reduction of the postoperative pain and swelling in lower extremity injuries which require external fixation.

Technical Approach: Patients receiving external fixation devices will be randomized into two groups. Both groups will receive DVT prophylaxis which includes subcutaneous heparin and Ectorin when ambulatory. Group A will receive an AVI Foot Pump which they will wear during nonambulatory hours. Group B, which will not receive the device, will receive the normal standard of care. All patients will undergo measurements of postoperative swelling of the mid thigh, and proximal and distal calf on POD 1, 2, 3, 5 and 7. Patients will also undergo subjective and objective evaluations of pain and medication requirements for pain for two weeks.

Progress: Study not pursued. Principal investigator PCSd from Brooke Army Medical Center.

### Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-29-91 Status: Completed

Title: Estimation of the Maximum Rate of Oxygen Consumption - A New Approach.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Richard B. Hecker, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Critical Care	Associate Investigator(s): James M. Lamiell, COL, MC James Parker, CPT, MC Glen Gueller, SFC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9

Total number of subjects enrolled to date: 17

Periodic review date: 27 Oct 92 Review results:

Objective(s): To estimate the maximum rate of oxygen consumption of healthy adult volunteers using a modified Harvard Step Test and compare the results with actual measured values of  $\dot{V}O_{2\max}$  obtained from an oxygen analyzer system.

Technical Approach: Thirty volunteers will undergo a modified Harvard Step Test. The volunteers will have heart rate monitored via standard 5 lead ECG. They will then be asked to mount a bicycle ergometer and provide a period of maximum exertion.

Progress: There has been no new progress since last annual report. This study suffers from a lack of support personnel. The main laboratory technical assistant (SFC Gueller), who is also an associate investigator, has been tasked with numerous projects. SFC Queller has now retired from the U.S. Army and his future participation in this project is in question. Technical equipment for this project can be located in the Department of Clinical Investigation. The project will be continued at this time. Discussion with the other principal investigator (Dr. Parker) will be continued. Consents, data sheets, etc. are on file in the office of Dr. Hecker.



# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-30-91 Status: Terminated

Title: Effects of Blood Transfusion on the Metabolic Rate as Measured by Indirect Calorimetry.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Joseph P. Ducey, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To measure, using indirect calorimetry, the effect of blood transfusion on the metabolic rate of intraoperative, postoperative and critically ill patients.

Technical Approach: The effect of blood transfusion on the metabolic rate of intraoperative, postoperative and critically ill patients will be measured by indirect calorimetry. We will also measure the concomitant effects of inotropic agents, paralyzing agents, mechanical ventilation, hypothermia, electrolyte and acid base disorders on O<sub>2</sub> utilization during and immediately following a blood transfusion.

Progress: Study terminated. Principal investigator PCS'd from Brooke Army Medical Center.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-40-91                      Status: Terminated

Title: Physiologic Testing of a Chemical Warfare Agent Protective Patient Wrap.

Start date: 6 Mar 91	Estimated completion date:
Principal Investigator: Charles P. Kingsley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): David L. Danley, MAJ, MS Richard Hecker, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 7 Oct 92                      Review results: \_\_\_\_\_

Objective(s): To evaluate the ambient oxygen and carbon dioxide concentrations that are present during encapsulation in a threat agent protective patient wrap (WRAP).

Technical Approach: Twelve human volunteers will be encapsulated in a chemical agent protective patient wrap. During a three hour study period temperature, heart rate, minute ventilation and inspired and exhaled oxygen and carbon dioxide concentrations will be recorded. The effects of supplemental oxygen, air and air circulation within the wrap will be studied.

Progress: Study terminated. Investigator has ETS'd from the Army.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-48-91 Status: Terminated

Title: A Comparison of Postoperative Sore Throat in Patients Who Receive Succinylcholine or Vecuronium for Endotracheal Intubation.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Donald B. Tallackson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service:	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 45

Total number of subjects enrolled to date: 50

Periodic review date: Review results:

Objective(s): To determine whether the administration of succinylcholine to facilitate endotracheal intubation increases postoperative sore throat when compared to vecuronium administration.

Technical Approach: Eighty women undergoing intra-abdominal procedures will be randomized to receive succinylcholine or vecuronium at the time of endotracheal intubation. Anesthesia will be standardized and variables known to affect sore throat will be controlled. Patients will be interviewed postoperatively to determine severity and incidence of sore throat and hoarseness.

Progress: Study terminated. Principal investigator has PCS'd from Brooke Army Medical Center.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-50-91                      Status: Ongoing

Title: Comparison of Trigger Point Injections Using Kerolac Tromethamine versus Saline in the Treatment of Myofacial Pain Syndrome.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Roger L. Wesley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): William Strong, MAJ, MC
Key      is:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if kerolac tromethamine is effective in providing pain relief in myofascial pain syndrome, and if so, for how long.

Technical Approach: Fifty adult volunteers who are referred to the pain clinic with myofascial pain syndrome will be enrolled in the double blinded, randomized study. Pain intensity and quality will be assessed using pressure algometry all visual analog pain scales. Patients will then be given trigger point injection with either ketorolac tromethamine or saline in a double blinded fashion. Pain reassessment will be done at 10 minutes, 6 hours, 1 day and 1 week following injection.

Progress: Principal investigator has no definitive data to report.

# Detail Summary Sheet

Date: 31 Dec 93 Protocol Number: C-56-91 Status: Ongoing

Title: Urine Flow Rate Pre- and Post-Penile Prosthesis Implantation.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Kevin C. Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine 1) those patients with bladder outlet obstruction secondary to benign prostatic hypertrophy prior to penile prosthesis implantation and 2) the incidence and degree of decreased urine flow rate secondary to penile prosthesis induced urethral obstruction.

Technical Approach: All patients scheduled for penile prosthesis implantation will complete a questionnaire and undergo pre- and postoperative urine flow rate utilizing the Dantec Uroflowmeter<sup>®</sup>.

Progress: Current status is uncertain. Principal investigator did not provide an annual report.

# Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: C-73-91      Status: Ongoing

Title: Does Magnesium Decrease the Incidence and Severity of Post-Cardiopulmonary Bypass Arrhythmias? A Double Blind, Randomized, Placebo Controlled Clinical Trial.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Janet Hays, MAJ, MC Greg Bowman, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0

Periodic review date:      Review results:     

Objective(s): 1) To determine the correlation of mononuclear blood cell (MBC) Mg concentrations with myocardial Mg concentrations.

2) To determine the correlation of myocardial and MBC Mg concentrations with post-CPB arrhythmias (ventricular and supraventricular).

3) To determine if MgSO<sub>4</sub> administration (30 mg/kg followed by 15 mg/kg/hour x 4 hours) is efficacious in reducing the incidence of post-CPB arrhythmias.

4) To determine the correlation of right atrial and left ventricular myocardial Mg concentration.

Technical Approach: Patients will be randomized to receive either 30 mg/kg MgSO<sub>4</sub> or placebo (normal saline) during CPB followed by 15 mg/kg/hour or placebo for four hours. The right atrial appendage (200 mg) will be sampled for intracellular Mg concentration. A left ventricular myocardial sample (200 mg) will be obtained if the left ventricle is to be incised for valve repair or aneurysmectomy. Myocardial samples will be obtained prior to the administration of the study medication. The detection method for arrhythmias will be a continuous Holter monitoring (leads CM5 and II) both pre- and

C-73-91 (continued)

post-CPB.

Progress: We are still awaiting laboratory support for the magnesium levels from Department of Clinical Investigation.

# **Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-74-91                      **Status:** Ongoing

**Neoadjuvant Hormonal Therapy Prior to Radical Prostatectomy for Clinical Stage A and B Carcinoma of the Prostate.**

<b>Start date:</b> 30 Aug 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> LTC Ian Thompson, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Urology	<b>Associate Investigator(s):</b> Eric J. Ziedman, LTC, MC Edward J. Mueller, LTC, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 6  
**Total number of subjects enrolled to date:** 6  
**Periodic review date:** 14 Sep 93      **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine if neoadjuvant hormonal therapy prior to radical prostatectomy results in an improvement in pathologic stage of carcinoma of the prostate. 2) To determine whether complication rates are reduced following radical prostatectomy which is preceded by neoadjuvant hormonal therapy.

**Technical Approach:** Sixty patients with clinically stage A1, B1, B1 (t1-2) carcinomas of the prostate will be randomized to receive either radical prostatectomy or adjuvant hormonal therapy. Patients eligible for the study must have a negative staging evaluation including normal bone scan and no evidence of extraprostatic disease. All patients will have preoperative PSA and acid phosphatase drawn and assigned a Gleason's histologic grade.

**Progress:** **NOTE:** This study was reported as completed in FY 92 annual research progress report. This was incorrect. The study is ongoing. An adverse experience occurred on one patient and was reported to IRB on 11 Aug 93. Appropriate intervention was made and patient's condition improved.



# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-75-91 Status: Terminated

Title: Influence of Injectate Temperature on Spinal Anesthesia with Isobaric Lidocaine.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Douglas J. Loughhead, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Kevin Kenworthy, CPT, MC Cheryl Wesen, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the effect of injectate temperature (37°C vs 20°C) during isobaric lidocaine spinal anesthesia with respect to 1) onset of blockade, 2) maximum sensory level of blockade attained, 3) quality of analgesia, and 4) duration of blockade.

Technical Approach: This is a randomized, double blind, prospective study. Adult male patients scheduled for inguinal herniorrhaphy are eligible to participate. They will be randomized to receive spinal anesthesia with isobaric lidocaine equilibrated to 20°C or isobaric lidocaine equilibrated to 37°C.

Progress: Study terminated. Principal investigator has PCS'd from Brooke Army Medical Center.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-76-91 Status: Ongoing

Title: Efficacy of Steroid in Reducing Post-Tonsillectomy Morbidity.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: James Lee, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department ( Surgery/Otolaryngology	Associate Investigator(s): Sylvester G. Ramirez, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18

Total number of subjects enrolled to date: 19

Periodic review date: Review results:

Objective(s): To determine whether the use of intravenous perioperative steroids (dexamethasone) enhances the overall recovery in patients undergoing tonsillectomy: (1) by reducing postoperative pain, 2) by reducing postoperative swelling, and/or 3) allowing improved oral intake.

Technical Approach: The study group will include approximately 50 study subject and 50 controls. This study will compare post-tonsillectomy 1) pain, 2) tolerance of diet, i.e., liquids vs soft vs regular, 3) swelling, 4) temperature 5) weight fluctuation and 6) complications between patients receiving dexamethasone or placebo perioperatively.

Progress: Thus far, 19 patients have enrolled out of an anticipated 100 needed. We have had several patients refuse this study, and have also had patients that did not have study offered erroneously. Will forward information to patients prior to surgery in effort to increase our rate of participation.

Study ongoing. We are changing the principal investigator to CPT James Lee, MC. He is familiarizing with background and will start to enroll more patients.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-89-91                      Status: Completed

Title: Open Label Trial of Centoxin (HA-IA) Treatment of Presumed Gram-Negative Sepsis

Start date: 7 October 1991

Estimated completion date:

Principal Investigator:  
Richard B. Hecker, CPT, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Surgery/SICU

Associate Investigator(s):  
J. William Kelly, MAJ, MC  
David P. Ciceri, MAJ, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 15

Total number of subjects enrolled to date: 17

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To provide a means by which a critically ill patient with presumed gram-negative sepsis may receive investigational HA-1Atreatment.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: FINAL REPORT. A total of 17 doses of 100 mg HA-IA were administered IAW established protocol to 11 subjects. Four patients received multiple doses (two patients received 2 doses; two patients received 3 doses). Of the 11 patients, 6 died and the other 5 were discharged from the surgical ICU.

## SUMMARY:

Single dose: N=7    Alive = 3    Dead = 4

Double dose: N=2    Alive = 0    Dead = 2

Triple dose: N=2    Alive = 2    Dead = 0

# Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: C-90-91      Status: Ongoing

Title: Phase I Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Metastatic Cancer of the Prostate.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Peter Randin, MC Edward J. Mueller, LTC, MC Eric J. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 4

Periodic review date:      Review results:     

Objective(s): 1) To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer.

2) To determine if immunization against LHRH will cause suppression of luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels in these patients.

3) To observe patients for signs of adverse effects following immunization.

Technical Approach: Four patients from BAMC will be referred on the study. The LHRH vaccine will be administered by Dr. Ravdin at the University of Texas Health Science Center on three occasions at two week intervals. Patients will return to BAMC for follow-up at monthly intervals for the first six months and then every three months for up to two years.

Progress: Four patients are currently being followed. There have been no changes thus far. Followup will be continued at appropriate intervals.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-91-92                      Status: Ongoing

Title: Does Preoperative Axillary Ultrasound and Tumor DNA Content Predict Axillary Lymph Node Metastases in Breast Cancer Patients with Clinically Negative Axilla.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Frank M. Robertson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To prospectively analyze a group of variables to include age, size of primary tumor, receptor status, presence of adenopathy on axillary ultrasound, ploidy status and percent s-phase in breast cancer patients with clinically negative axilla.

Technical Approach: Data to include age, primary tumor size, estrogen receptor status, progesterone receptor status, axillary ultrasound, ploidy status, s-phase fraction, and final anatomic pathology results will be collected on all patients treated for breast cancer at BAMC for a period of 18 to 24 months. In patients with suggestive physical exams or mammograms, the ultrasound will be obtained prior to any surgical intervention such as biopsy.

Progress: This protocol is still in a hold status. A lack of ultrasound technical support has been the problem.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-26

Status: Ongoing

Title: Determination of Vecuronium Bromide Requirements in Nonthermally Injured Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the ED<sub>50</sub> of vecuronium bromide for train-of-four twitch height depression in the nonthermally injured patient. 2) To compare the ED<sub>50</sub> determined for these patients to that determined for thermally injured patients.

Technical Approach: Patients will be premedicated at the discretion of the anesthesiologist. After placement of monitors and preoxygenation, patients will be induced with sufentanil citrate and thiopental sodium or ketamine as indicated by the patient's condition.

Progress: Three study patients (ISR) are needed to complete study.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-27                      Status: Completed

Title: Analysis of Foot Surface Stress in Parachute Landing Falls

Start date:	Estimated completion date:
Principal Investigator: CPT James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Robert Harris, MC
Key Words: PLF's Foot Surface Stress	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period:   0    
 Total number of subjects enrolled to date:   0    
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To analyze foot surface stress in PLF-s under varying conditions (footgear, terrain, velocity) utilizing an in-shoe foot force analysis system. This data will be used to: 1) understand the mechanics of high impact landing; 2) design and test equipment to protect paratroopers during airborne missions; and 3) recommend changes in training regimens and landing techniques.

Technical Approach: All jumps will be performed from a platform or a horizontal "slide" by U.S. Army paratroopers on active jump status. An F-scan force analysis system will be used to measure landing forces during all jumps. System consists of an in-shoe transducer that is made up of 960 element matrix of 5mm square sensors linked to a 386 computer.

Progress: Study completed. Results currently being developed.

# Detail Summary Sheet

Date: 31 Dec 93                      Protocol Number: C-92-29                      Status: Terminated

Title: The Use of Conjunctival Impression Cytology in Thermally Injured Patients

Start date:	Estimated completion date:
Principal Investigator: CPT Mary C. Conaway, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s): CPT Ben Chacko, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To characterize the changes in conjunctival cellular morphology in thermal injury.

Technical Approach: This prospective descriptive study seeks to establish a simple and safe procedure for characterizing the morphologic changes in the conjunctival epithelium of thermally injured patients. 1) Study is designed to collect admission samples of surface epithelium using impression cytology. The patients will be re-evaluated at regular intervals of 72 hours, one week, two weeks, three weeks, and four weeks using the same technique. The character and extent of morphologic changes will be compared to normal patients devoid of ocular surface disease.

Progress: Study is terminated due to PCS of principal investigator to Ft. Bragg, North Carolina and inactivity since her departure.



Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-35 Status: Ongoing

Title: Use of a Foot Compression Pump in the Prevention of Deep Vein Thrombosis in Hip Fractures

Start date:	Estimated completion date:
Principal Investigator: CPT James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Robert Harris, MC CPT Brian Allgood, MC COL Allan Bucknell, MC
Key Words: DVT, Foot Pump Total Joint Arthroplasty	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 29  
Total number of subjects enrolled to date: 40  
Periodic review date: 13 Dec 93 Review results: \_\_\_\_\_

Objective(s): To determine the clinical usefulness of the AVI foot pump as prophylaxis for deep venous thrombosis associated with hip fractures in individuals greater than 40.

Technical Approach: All male and female patients greater than 40 years of age sustaining a femoral neck fracture of intertrochanteric fracture presenting to the BAMC Orthopaedic Surgery Service within 48 hours of injury and requiring operative intervention without a history of prior deep venous thrombosis, without concomitant lower extremity precluding the use of a foot pump, not on warfare in therapy for other medical problems, and not pregnant will be eligible for inclusion in the study.

Progress: Seventy-five patients enrolled on study but not enough for achievement of statistical signs.

### Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-42

Status: Terminate

Title: Superoxide Dismutase (r-hSOD) in the Management of Acute Head Injury

Start date:	Estimated completion date:
Principal Investigator: Steven L. Klein, LCDR	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Neurosurgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy of r-HSOD in the management of severe acute head injury. To evaluate the metabolic, biochemical, and vascular drug related responses to head injury in humans.

Technical Approach: As indicated in the protocol.

Progress: This study was held up for greater than one year by FDA. Study was never started and the Principal Investigator has left the military.

# **Detail Summary Sheet**

**Date:** 15 Dec 93  
**Ongoing**

**Protocol Number:** C-92-45

**Status:**

**Title:** The Incidence of Sexual Dysfunction After Transurethral Prostate Surgery Using Rigiscan Penile Tumescence and Rigidity Device

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Duane Cespedes, CPT, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Urology	<b>Associate Investigator(s):</b> Ian M. Thompson, LTC, MC Eric J. Zeidman, MAJ, MC Samuel Peretsman, MD Alvin L. Sago, COL, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the qualitative and quantitative effect of transurethral surgery upon erectile potency as measured by both sexual function instruments (inventory/questionnaire) and by Rigiscan tumescence/rigidity monitoring.

**Technical Approach:** All patients will be asked to complete a standardized sexual function questionnaire. Rigiscan monitoring will be performed on all patients within two months prior to prostate surgery and again three months following surgery. If at the three-month interval, the patient is experiencing any medical or physical problem which might interfere with the Rigiscan interpretation, the Rigiscan testing will be postponed for a clinically-appropriate period.

**Progress:** This study is on hold as prostatectomy is changing to a laser procedure. When the persistent pattern emerges, patient entry will begin.

**Detail Summary Sheet**

**Date:** 31 Dec 93                      **Protocol Number:** C-92-47                      **Status:** Ongoing

**Title:** Acute Normovolemic Hemodilution: Comparison of the Use of Mixed Venous Oxygen Saturation to a Standard Technique

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> CPT Paul D. Mongan, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/Anesthesiology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b> \$33,386.00

**Number of subjects enrolled during reporting period:** 6  
**Total number of subjects enrolled to date:** 6  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To evaluate a standard technique of hemodilution with regard to cardiovascular changes and compare this information to the safe limits of hemodilution which we will establish. 2) To establish the limits of safety of this technique based on recognized physiologic parameters by using mixed venous oxygen saturation as a guide to limit the amount of blood removed and to guide the need for transfusion therapy.

**Technical Approach:** Written informed consent will be obtained from the parents of 20 healthy patients scheduled for major spine surgery. A routine preoperative assessment will be performed by the anesthesia team and preoperative laboratory tests will be obtained. All patients will have anesthesia induced via mask with oxygen, nitrous oxide and halothane or with the intravenous agent thiopental. Intubation will be facilitated by the use of vecuronium bromide at a dose of 0.1 mg/kg.

**Progress:** One patient will be enrolled in December 1993.

**Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-92-48                      **Status:** Terminate

**Title:** Nitrate Metabolism in Critically Ill Patients.

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Frank M. Robertson, MAJ, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Critical Care	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To measure urinary nitrate and urea levels in critically ill patients using the stable isotope-N15-arginine, and compare these with normal controls.

**Technical Approach:** A group of 4-8 critically ill patients with sepsis and/or multiple organ failure will be compared to a similar group of stable general surgery patients.

**Progress:** Principal investigator has left the military service and gone to Boston. There are no plans to pursue study.

**Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-92-57                      **Status:** Ongoing

**Title:** Prostatic Intraepithelial Neoplasia as a Predictor of Subsequent Development of Carcinoma of the Prostate.

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Ian M. Thompson, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Urology	<b>Associate Investigator(s):</b> COL Moo Cho, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the association of PIN and AAH with subsequent development of CAP in men with benign prostatic hyperplasia (BPH).

**Technical Approach:** The slides of the pathologic evaluation of the benign glands in the 333 men who underwent TURP for BPH between 1980 and 1983 will be recovered. The slides will then be forwarded to Dr. Michael Brawer at the University of Washington for evaluation. The evaluation will be made in a 'blinded' manner - i.e., Dr. Brawer will not be aware of which patients subsequently developed carcinoma of the prostate.

**Progress:** This study still has yet to be activated. We are currently awaiting support from the VA Cooperative Trials group for pathologic processing.

# Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-60

Status: Ongoing

Title: A comparison of intraoperative patient controlled sedation with sedation provided by an anesthesiologist for surgery performed under regional anesthesia.

Start date: Mar 92	Estimated completion date: Jun 93
Principal Investigator: John C. Talbot, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Joseph P. Ducey, LTC, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 38  
 Total number of subjects enrolled to date: 38  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare intraoperative patient controlled sedation administered on demand by a PCA infuser, with sedation provided by an anesthesiologist during regional anesthesia. The study will evaluate the feasibility of patient controlled sedation, patient and physician acceptance of this method, as well as patient benefits and adverse effects.

Technical Approach: Forty (40) ASA I and II adult patients (ages 18-70) scheduled for elective surgery under spinal or regional anesthesia will be investigated. Patients will be randomized into two groups. No pre-op sedations, hypnotics or opioids will be given. Routine monitors will be applied (continuous ECG, pulse oximetry, automated oscillometric blood pressure, nasal CO<sub>2</sub> and precordial stethoscope), and patients will be placed on 3 liters per minute oxygen by nasal prongs. Patients in groups one and two will receive a bolus of 0.5mg/kg of propofol over 2 minutes before performing the regional anesthetic.

Progress: Dr. Mongan to check with Dr. Talbot on progress.

**Detail Summary Sheet**

**Date:** 31 Dec 93                      **Protocol Number:** C-92-66                      **Status:** Ongoing

**Title:** Impact of Dietary Manipulation on Prostate Cancer

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Ian M. Thompson, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Urology	<b>Associate Investigator(s):</b> Barbi Helfrick, RN Susan Wise Wilson, MS, RD, LD Forrest Newman, LTC, MC Jean M. Johnson, Ph.D., RN
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine if a low fat, high fiber diet reduces serum prostatic specific antigen (PSA) in patients with carcinoma of the prostate. 2) To assess the impact of a low fat, high fiber diet on a patient's quality of life. 3) To assess the relationship between health beliefs, self-efficacy, social support and compliance with a low fat, high fiber diet.

**Technical Approach:** Pilot study will describe the impact of dietary manipulation on serum PSA, the factors which may contribute to dietary compliance, and the overall effect on quality of life. Subjects will be their own controls. The study group will consist of thirty men with known carcinoma of the prostate identified through the Urology Service Tumor Registry and who have (1) stable disease, (2) intact hormonal axis, and (3) elevated PSA (greater than 4 ng/ml as measured by the Hybritech assay). All men will be informed as to the nature of the study and will sign informed consent.

**Progress:** The first stage of this study has been completed with modest changes noted in PSA. A larger study (this one) has entered 7 patients on the diet trial and accrual continues.



# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-67 Status: Ongoing

Title: Pilot Study of Intravesical Bacillus Calmette-Guerrin (BCG) Therapy for Refractory Interstitial Cystitis.

Start date: 30 Jul 91	Estimated completion date:
Principal Investigator: Eric J. Zeidman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC Edward J. Mueller, LTC, MC Paul M. Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5

Total number of subjects enrolled to date: 5

Periodic review date: Review results:

Objective(s): To determine if intravesical Bacillus Calmette-Guerrin therapy results in an improvement in interstitial cystitis pathologic signs and symptoms.

Technical Approach: Ten patients (in stages of five) with refractory interstitial cOystitis will be given six weekly intravesical treatments with one vial of Bacillus Calmette-Guerrin (BCG) vaccine. Patients will undergo cystoscopy under anesthesia before entrance into the study to ensure documented glomerulations upon second fill and biopsy proven absence of carcinoma in situ. Symptoms questionnaires will be filled out by the patient prior to BCG therapy, and at 3,6, and 12 months following therapy. If after ten patients we find a significant response to this therapy, we will submit another protocol.

Progress: The study is complete. All patients had some degree of response. For this reason, the study was closed after 5 patinets. A randomized prospective trial is in the offing.

### Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: C-92-74

Status: Ongoing

Title: A Preliminary Study on Multiple Linear Regression Analysis of Apnea Indices as a Function of Cephalometric Measurements in Preoperative and Postoperative Patients

Start date:	Estimated completion date:
Principal Investigator: CPT John H. Romanow, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s): MAJ Sylvester Ramirez, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): A preoperative cephalogram and polysomnogram will be obtained in adult patients and compared to published norms.

Technical Approach: As part of their evaluation at the sleep clinic at BAMC, patients undergo a workup consisting of a history and physical, spirometry, TFTs, ABGs, cephalometric analysis and polysomnography. This is a preliminary study and thirty patients will be chosen who have OSA by polysomnography and choose surgical therapy.

Progress: Study ongoing as part of sleep study protocol C-92-81.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-84                      Status: Terminated

Title: Treatment of Stage C Carcinoma of the prostate with Adjuvant Hormonal Therapy Followed by Radical Prostatectomy.

Start date:	Estimated completion date:
Principal Investigator: LTC Ian M. Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the potential benefit of neoadjuvant hormonal therapy on the disease free survival rates in Stage C (T3NOMO) carcinoma of the prostate. 2) To assess the qualitative and quantitative toxicities of patients with Stage C prostate carcinoma with androgen blockade followed by surgery. 3) To assess the effect of neoadjuvant hormonal therapy on prostate intra-epithelial neoplasia (PIN).

Technical Approach: All eligible patients will receive neoadjuvant hormonal therapy prior to radical prostatectomy. Twenty eligible patients will be recruited.

Progress: This study has been closed due to a SWOG study with similar endpoints opening.

**Detail Summary Sheet**

**Date:** 15 Dec 93

**Protocol Number:** C-92-91

**Status:** Terminated

**Title:** Hormonal Influences on Cultural Osteoblasts from Mature and Senile Rats

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Jay D. Mabrey, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/Orthopaedic Surgery	<b>Associate Investigator(s):</b> Mona M. Everett, Ph.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To study the effects of aging on osteoblasts. We will compare osteoblasts cultured from mature rats (8 months of age) to those of a population of senile rats (24 months of age). Parameters examined will be osteoblast plating efficiency, cell growth, alkaline phosphatase activity and distribution, alkaline phosphatase characteristics, and response of cultured osteoblasts to hormones.

**Technical Approach:** Bone fragments from the long bones of mature and old Fischer 344 rats will be cultured in 25 cm<sup>2</sup> flasks. In addition to the appropriate vehicle controls, one of several agents will be added. Growth parameters, nodule formation, and bone-related markers will be measured.

**Progress:** Principal investigator ETSd. Study moved to University of Texas Health Science Center.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-10                      Status: Completed

Title: What should we monitor? Does site of neuromuscular blockade monitoring predict intubating conditions with Mivacurium: A comparison of the adductor pollicis and orbicularis oculi?

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: Samuel Sayson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): Paul D. Mongan, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 30  
 Periodic review date: Review results:

Objective(s): To determine if there is a difference in intubating conditions as defined by vocal cord position and patient response when monitoring for 95% T1 twitch height depression at the adductor pollicis versus the orbicularis oculi.

Technical Approach: Null Hypotheses. When using mivacurium chloride (0.15mg/kg) to facilitate endotracheal intubation, there is no difference in intubating conditions when twitch height depression monitored at the adductor pollicis of orbicularis oculi.

Progress: Thirty patients enrolled. Manuscript completed for publication pending revision.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-11      **Status:** Completed

**Title:** A Comparison of four Different Site Determinations of Body Temperature in the post-anesthesia Care Unit (PACU)

<b>Start date:</b> 2 Nov 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Richard B. Hecker, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/Critical Care Svc	<b>Associate Investigator(s):</b> Roxanne M. Darm, R.N. Bernard J. Rubal, Ph.D. Richard B. Hecker, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 215  
**Total number of subjects enrolled to date:** 215  
**Periodic review date:** \_\_\_\_\_ **Review results:** Completed

**Objective(s):** Patients that have undergone a surgical procedure in the operating room are at risk for hypothermia, with continuation of hypothermia in the Post Anesthesia Care Unit (PACU) being both a medical and nursing concern. At present, there is sparse documentation in the literature regarding the best method of temperature monitoring in the PACU. The objectives of this study are twofold. First, four methods for noninvasive monitoring of body temperature will be compared: Tympanic, oral, axillary, and forehead skin temperatures. Secondly, the per patient cost of temperature monitoring will be evaluated.

**Technical Approach:** This study will compare the ease and precision of use of four methods for monitoring body temperature in the PACU: Tympanic temperatures recorded utilizing an infrared sensitive electronic tympanic probe (FirstTemp Genius Model 3000A, Intelligent Medical Systems, Inc., Carlsbad, CA), oral and axillary temperatures measured using a thermistor tipped electronic probe (IVAC Temp Plus II, IVAC Corporation, San Diego, CA), and core temperature corrected LCT forehead temperature strips (Sharn Inc., Tampa, FL). Study population and further criteria outlined in protocol.

**Progress:** Completed with abstract publication, poster presentation and paper submission.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-15                      Status: Ongoing

Title: Multicenter Efficacy and Tolerability Study Comparing PROSCAR<sup>®</sup> (finasteride) and Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia

Start date: 8 Dec 92	Estimated completion date: Sep 94
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Leonard G. Renfer, M.D. Douglas A. Schow, M.D. Julius L. Teague, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12  
Total number of subjects enrolled to date: 12  
Periodic review date: 8 Dec 93      Review results: \_\_\_\_\_

Objective(s): To determine whether or not men with moderate BPH symptoms will improve significantly while taking Proscar (finasteride)

Technical Approach: Men of primarily Afro-American and Hispanic descent with moderate BPH symptoms are placed on Proscar for a period of one year after screening for prostate cancer. 80% of patients are placed on drug, 20% on placebo. Patients are monitored at 3 month intervals for status of urinary symptoms and occurrence of adverse experiences.

Progress: To date, two patients have chosen to discontinue the study due to lack of improvement of symptoms and all others are the same or improved.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-21                      Status: Terminated

Title: The Use of Intraarticular Narcotics to Control Facet Joint Pain

Start date: 16 Nov 92	Estimated completion date:
Principal Investigator: Samuel C. Sayson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesia & Operative	Associate Investigator(s): John Talbot, M.D. Tara Chronister, M.D. Joseph Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish the effect of intraarticular morphine sulfate on low back pain related to facet joint disease.

Technical Approach: Null hypotheses, patient population, experimental design, methods, data collection and statistical analysis outlined in protocol.

Progress: Analysis shows no expected difference between groups.



# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-23      Status: Ongoing

Title: Phase III Trial of Coumarin (1, 2, -Benzopyrone) in Patients with Clinically Localized Prostatic Carcinoma Treated by Radical Prostatectomy Found Pathologically to Have High Risk of Recurrence

Start date: Jan 93	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The objectives of this Phase III study of Coumarin (1,2-benzopyrone) in patients with carcinoma of the prostate treated by radical prostatectomy who are at high risk of recurrence are to:

1. Determine whether coumarin therapy prevents progression or delays time to progression compared to placebo.
2. Evaluate the qualitative and quantitative toxicities of coumarin administered for prolonged periods.

Technical Approach: The coumarin therapy including drug information details, eligibility criteria, descriptive factors, pretreatment evaluation and treatment plan are outlined in protocol.

Progress: One patient has entered this trial. The patient has a long history of irritable bowel complaints which are unchanged. His disease status is undetermined at this point.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-29      Status: Ongoing

Title: Heart Valve Allograft CryoLife Cardiovascular, Inc. Non-Primary Clinical Protocol

Start date: 19 Dec 92	Estimated completion date:
Principal Investigator: Greg Bowman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s): David J. Cohen, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: \$25,000.00

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: 12/17/93      Review results: ?

Objective(s): To develop the safety and efficacy data for the cryopreserved heart valve allograft which will support FDA approval for the continued distribution of these heart valves as a replacement or a treatment for diseased, damaged, malformed, or malfunctioning aortic or pulmonary heart valves.

Technical Approach: Patient population, inclusion/exclusion criteria and further specifics are in protocol.

Progress: Cryopreserved homograft aortic valves have been implanted in 4 patients and a cryopreserved hemograft aortic root has been implanted in 1 patient. There have been two deaths in the study. One death was unrelated to prosthetic valve choice and confirmed by post mortem. The second death ultimately resulted from graft failure, but severe acute mediastinitis was the underlying cause. It is most likely the death would have occurred no matter what the choice of prosthesis. What was learned in this case was that early graft coverage is extremely important when the allograft is exposed.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-32      Status: Ongoing

Title: Evaluation of Gastroesophageal Reflux in Preterm Infants

Start date: 1 Jan 93	Estimated completion date:
Principal Investigator: Russell J. Otto, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Otolaryngology	Associate Investigator(s): Judith O'Connor, M.D. Howard Heiman, M.D. Deborah M. Burton, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether gastroesophageal reflux (GER) can be reliably evaluated in intubated premature neonates. Sequential cases will be considered for inclusion in the study. The study population will consist of mechanically ventilated infants approximately 25-36 weeks gestational age.

Technical Approach: The proposed study will prospectively examine premature neonates in the 25-36 week gestational age range who meet the inclusion criteria. Inclusion criteria are infants requiring mechanical ventilation and tolerating enteral feeding. Exclusion criteria are full term infants, infants with symptoms associated with GER, infants with craniofacial disorders, neuromuscular disorders, syndromes associated with GER, or processes that mimic GER such as food intolerance, malabsorption, renal or infectious problems. Further details covered in protocol.

Progress: No results compiled at this time.

# Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-36 Status: Terminated

Title: The Use of an Electromechanical Pressure Transducer to Identify the Perineural Space During Placement of Axillary Brachial Blocks

Start date: Dec 92	Estimated completion date:
Principal Investigator: Douglas J. Loughhead, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This is a prospective study to evaluate the usefulness of monitoring the pressure waveform generated by a saline-filled pressure transducer system attached to a standard block needle while performing an axillary brachial plexus block.

Technical Approach: The axillary approach to brachial plexus blocks is a well established method for providing surgical anesthesia for procedures on the forearm and hand. For vascular procedures, vasodilatation from regional sympathectomy is an added benefit of this technique which allows for greater blood flow to the affected site. Study population, hypothesis, exclusion criteria and specifics outlined in protocol.

Progress: All Principal Investigators transferred. No patients enrolled/no data to report.

# Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-38 Status: Terminated

Title: The Management of Femoral Shaft Fractures in Thermally Injured Patients

Start date: 9 Dec 92	Estimated completion date:
Principal Investigator: Doug A Vermillion, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedic Surgery	Associate Investigator(s): David W. Mozingo, M.D. S.L. Martin, M.D. Al Bucknell, M.D. W.F. McManus, M.D. B.A. Pruitt, Jr., M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The care of orthopaedic injuries in the burn victim population is controversial. There is a trend in the trauma literature to treat injuries in a more aggressive manner to lessen the rate of pulmonary complications, provide for ease of nursing care, and for patient comfort. This study has a larger number of burn victims with fractures than other studies and this review will provide useful information for orthopedists and burn physicians on how best to manage these complex patients.

Technical Approach: The data has been collected and the presentation will be made at the Society of Military Orthopaedic Surgeons meeting and most likely at the American Burn Association meeting next spring pending approval by the ISR.

Progress: Principal Investigator transferred; study closed.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-42      Status: Ongoing

Title: A Comparison of Six Different Intraoperative Site Determinations of Body Temperature Compared to Core Blood Temperature

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Scott T. Davis, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative	Associate Investigator(s): Richard B. Hecker, M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25  
 Total number of subjects enrolled to date: 10  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

**Objective(s):** Patients undergoing surgical procedures are at risk for thermal perturbations. Most patients become hypothermic during surgery, although a few become hyperthermic. Temperature changes in either direction can be a cause of complications requiring treatment. The best technique for accurate measurement of intraoperative temperature remains a point of controversy. The objective of this study is to compare seven methods for noninvasive monitoring of body temperature: Tympanic, esophageal, oral, bladder, nasopharyngeal, rectal and forehead skin temperatures against core blood temperature as measured from the pulmonary artery.

**Technical Approach:** This study will compare the accuracy and precision of seven methods for monitoring body temperature in the operating room. Tympanic temperatures will be recorded utilizing an infrared sensitive electronic tympanic probe. Esophageal temperatures will be measured using an esophageal stethoscope/temperature probe placed in the distal esophagus. Further specifics outlined in protocol.

**Progress:** Due to the limited number of vascular patients needing PA cath (AAA repair) and resident availability, only 10 patients have been placed in study in 12 months, therefore we have decided to use cardiac patients since the

C-93-42 (continued)

volume of such patients is higher at BAMC and would allow us to get our series of 25 patients in a reasonable amount of time. It would also not adversely affect said patients. We will also use bladder/nasopharyngeal temperatures. Our measurements will be made within 30 minutes of induction.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-46      **Status:** Ongoing

**Title:** Serum Prostate Specific Antigen (PSA) Levels Before and After Vasectomy

<b>Start date:</b> 18 Feb 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Ian M. Thompson, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/Urology	<b>Associate Investigator(s):</b>  Julius Teague, M.D. Cathy Pollard, R.N. Barbi Helfrick, R.N.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the relationship between serum PSA levels and vasectomy.

**Technical Approach:** The BAMC Urology Clinic presently does 12-15 vasectomies per month for elective permanent sterility. There is a mandatory group briefing for patients and their partners prior to the procedure. Fifty patients who volunteer at these briefings will be asked to have blood drawn for determination of PSA before, one week after, one month after, and six months after bilateral vasectomy for permanent surgical sterility. Patients who've had prior vasectomy will be excluded. Patients will be their own controls and the data analysis will be performed using students T test. The study group of 50 patients is reasonably sized and data accrual time will be prompt. Should trends in data suggest significant differences in PSA before and after vasectomy, the study could be extended to accrue larger more significant study population.

**Progress:** An initial evaluation of patients accrued thus far demonstrates no change in PSA.



# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-48                      Status: Ongoing

Title: Clinical Evaluation of Left Ventricular Assist Device

Start date: 12 Mar 93	Estimated completion date:
Principal Investigator: David J. Cohen, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This study is designed to evaluate the use of a Pierce-Donachy Paracorporeal Ventricular Assist Device for patients with one of three problems: 1) post open heart surgery cardiac failure, 2) post myocardial infarction cardiogenic shock, and 3) cardiomyopathy when patients are awaiting heart transplantation and no donor hearts are available. This device is intended for use in patients with heart failure who would otherwise be unable to be supported through conventional medical means. The device would be used for a relatively short period (two to ten days) until either cardiac function returns to a level sufficient to allow for device removal or, in the case of "bridge to transplant," until a donor heart is available. If approval of this project is obtained, we hope to be named an investigational site by the Thoratec Corporation under agreement with the Food and Drug Administration.

Technical Approach: Outlined in protocol.

Progress: Has yet to be activated. Pending receipt of funds.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-50      **Status:** Terminated

**Title:** A Comparison of Single Versus Multiple Level Intercostal Nerve Blockade for Post-cholecystectomy Analgesia

<b>Start date:</b> 23 Jan 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Brian Thwaites, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/Anesthesiology	<b>Associate Investigator(s):</b> Don Tallackson, M.D. John Talbot, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine if single-level intercostal blockade with a large volume of local anesthetic is as effective as multiple-level intercostal blocks for post-cholecystectomy analgesia. Also to determine the efficacy of intercostal blockade in improving pulmonary function after cholecystectomy.

**Technical Approach:** The hypothesis to be tested is that single-level intercostal block with a large volume of local anesthetic is as effective as multiple-level intercostal blockade in providing post-cholecystectomy analgesia.

**Progress:** Very few candidates for study. Estimated completion would have been 3-4 years, therefore insufficient patient population to support study.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-51      Status: Ongoing

Title: Mandibular Reconstruction by Distraction Osteogenesis

Start date: 23 Mar 93	Estimated completion date:
Principal Investigator: Sylvester G. Ramirez, M.D.	Facility: Wilford Hall AFMC Brooke Army Medical Center, Texas
Department/Service: Surgery/Otolaryngology	Associate Investigator(s): Peter D. Costantino, M.D. USAF
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1. Reconstruct segmental mandibular defects in selected human subjects by applying distraction osteogenesis; and 2. Critically evaluate the efficacy of distraction osteogenesis for mandibular reconstruction in humans as compared to standard techniques.

Technical Approach: Methods, significance, risk/benefit ratio, and other specifics outlined in protocol.

Progress: To date no patients have been entered at BAMC. One patient was entered by Dr. Costantino at Wilford Hall AFMC.

Detail Summary Sheet

Date: 1 Dec 93

Protocol Number: C-93-62

Status: Closed

Title: Correlation of Penile Length and Risk for Carcinoma of the Prostate

Start date: 8 Feb 93

Estimated completion date:

Principal Investigator:  
Ian M. Thompson, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Surgery/Urology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish in a case-control study if there exists a correlation between penile length and risk of carcinoma of the prostate.

Technical Approach: Three groups of patients will be identified for study: Group One - men with diagnosed carcinoma of the prostate (CAP), Group Two - men with a diagnosis of benign prostatic hyperplasia (BPH), and men with a normal rectal examination and serum PSA less than 4 ng/ml. Specifics outlined in protocol.

Progress: This study is closed. No patients accrued. Data obtained from AUS refutes the hypothesis.

### Detail Summary Sheet

Date: 1 Dec 93

Protocol Number: C-93-68

Status: Ongoing

Title: Intraincisional Bupivacaine and Intramuscular Ketorolac for Post-operative Pain Relief After Laparoscopic Bilateral Tubal Electrofulguration

Start date: 25 Mar 93

Estimated completion date:

Principal Investigator:  
Christina L. Szigeti, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Surgery/Anesthesiology

Associate Investigator(s):  
Julius Szigeti, M.D.

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 15

Total number of subjects enrolled to date: 15

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the post-operative pain relief after operative laparoscopy and bilateral tubal electrofulguration (BTF) using intramuscular (IM) ketorolac alone, ketorolac with intraincisional bupivacaine and intraincisional bupivacaine alone. The total number of patients studied will be 128 (32 in each of the above groups plus a control group who will receive no study drugs). All patients will be American Society of Anesthesiologists (ASA) physical status I or II.

Technical Approach: Details including anesthesia, laparoscopic technique, pain evaluation and statistical analysis are outlined in protocol.

Progress: Collecting data.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-76      Status: Ongoing

Title: Phase I/II Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Cancer of the Prostate

Start date: 13 May 93	Estimated completion date:
Principal Investigator: Ian Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer, and to compare the effects of 2 immunization schedules. To determine if immunization against LHRH will cause suppression of luteinizing hormone (LHL) and follicle stimulating hormone (FSH) levels in men who have castrate testosterone levels, and cause a decrease in testosterone levels in men who have not undergone orchiectomy. To observe patients for signs of adverse effects following immunization.

Technical Approach: Protocol covers all specifics. It should be noted that all laboratory specimens will be obtained and assayed at UTHSCSA and no assays will be performed at BAMC. All immunizations will be performed at UTHSCSA. Additionally, it must be noted that although a total of 30 patients will be accrued to this protocol, this number is a total of both participating institutions.

Progress: No patients have yet been enrolled. Awaiting study drug.

Detail Summary Sheet

Date: 1 Dec 93

Protocol Number: C-93-78

Status: Ongoing

Title: The Use of EEG and Hemodynamic Parameters in the Design of Intelligent Anesthetic Control Systems

Start date: 14 May 93

Estimated completion date:

Principal Investigator:  
Douglas Anderson, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Surgery/Anesthesiology & Op

Associate Investigator(s):  
Paul Mongan, M.D.  
John Ward, Ph.D.

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2

Total number of subjects enrolled to date: 2

Periodic review date: Review results:

Objective(s): This study will collect hemodynamic and physiologic data in conjunction with raw EEG and Auditory evoked Responses from patients undergoing general anesthesia for surgical procedures. This data will be analyzed off-line for correlations of EEG changes with hemodynamic changes that are interpreted clinically as changes in anesthetic depth. Utilizing this information, signal processing techniques, adaptive control theory and artificial intelligence concepts will be applied to develop an anesthesiologist in providing patient care.

Technical Approach: This study is descriptive in nature and seeks only to assemble a data base of patient data for future study and analysis.

Progress: Two patients have been enrolled and data is being analyzed off-line to test theoretical algorithms.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-93      Status: Ongoing

Title: Determination of Preoperative Intravascular Volume Deficit in Bowel-Prepped Surgical Patients

Start date: 1 Jul 93	Estimated completion date:
Principal Investigator: Todd D. Storch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20  
 Total number of subjects enrolled to date: 20  
 Periodic review date: Review results:

Objective(s): To determine if oral bowel prep solutions as administered routinely prior to abdominal surgery, reduce intravascular volume in the adult surgical patient before surgery. Null hypothesis: Oral bowel preparation has no effect on preoperative intravascular volume status.

Technical Approach: 40 ASA physical status 1-3 patients, ages 18-65, presenting for elective surgical procedures will be enrolled in the study after written consent is obtained. Further specifics given in protocol.

Progress: Data for 13 patients thru 30 Sep 93 is valid. Data for 7 patient samplings done prior to 27 Jul discovery of incorrect spectrophotometer filter placement was rendered invalid.



### Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-93-91 Status: Ongoing

Title: Aeric and Particulate Microemboli as Etiologic Factors in the Development of Neurobehavioral Dysfunction Following Cardiopulmonary Bypass and Vascular Surgery: An Outcome Study.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Charles P. Kingsley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/ Anesthesiology	Associate Investigator(s): Maurice Albin, ND
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the incidence of air and particulate emboli during cardiopulmonary bypass (CPB) using transcranial doppler ultrasound as a detection device and to detect, correlate, and follow postoperative neurologic and psychometric changes seen in patients.

Technical Approach: This is a multicenter outcome study with UTHSCSA and Wilford Hall Medical Center. 125 patients requiring CPB will be enrolled with 25 patients for peripheral vascular procedures not requiring CPB serving as controls. Psychologic testing and neurologic evaluation will be performed preoperatively, at discharge and at 6 weeks, 6 months and 1 year after discharge. Intraoperative noninvasive testing will consist of transcranial doppler ultrasound (TCD) for the detection of air and particulate emboli and EEG monitoring by a commercially available processed EEG monitor. Anesthetic regimens will be standardized.

Progress: We still await funding by NIH.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-94      **Status:** Terminated

**Title:** Effect of Nitrous Oxide on Propofol Requirements During Total Intravenous Anesthesia (TIVA)

**Start date:** 1 Jul 93

**Estimated completion date:**

**Principal Investigator:**  
Daren Nigus, M.D.

**Facility:**  
Brooke Army Medical Center, Texas

**Department/Service:**  
Surgery/Anesthesiology & Operative Svc

**Associate Investigator(s):**  
D. Michael Anderson, M.D.

**Key Words:**

Gregory Bouska, M.D.

**Cumulative MEDCASE cost:**

**Estimated cumulative OMA cost:**

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the effect of nitrous oxide on the propofol dosage requirement and emergence time with intravenous anesthesia. Study design will be randomized and double-blind.

**Technical Approach:** Null hypothesis: Nitrous oxide has no effect upon propofol dosage requirements or emergence time with total intravenous anesthesia. Subjects, controls, data collection, statistical analysis and other specifics covered in protocol.

**Progress:** Terminated due to lack of interest since discharge of Principal Investigator.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-103      **Status:** Terminated

**Title:** Clinical and Microbiological Study Comparing Ciproflaxain Ophthalmic Solution to Tobrex Ophthalmic Solution for Treating Bacterial Conjunctivitis in Children

<b>Start date:</b> August 1993	<b>Estimated completion date:</b> 1 Nov 93
<b>Principal Investigator:</b> Mary O'Hara, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/Ophthalmology	<b>Associate Investigator(s):</b> John Roscelli, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b> 0	<b>Estimated cumulative OMA cost:</b> 0

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 0  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reactions for topical Ciprofloxacin Ophthalmic Solution against TOBREX in children (ages 1-12) with acute bacterial conjunctivitis. Acute is defined as having a duration of one week or less.

**Technical Approach:** Materials/methods, subjects, study procedure, etc., are outlined in protocol.

**Progress:** ALCON concluded the study before BAMC enrolled any patients.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-113      Status: Ongoing

Title: Effects of Desflurane on the Amplitude and Latency Characteristics of Brainstem Auditory, Midlatency Auditory, Median and Posterior Tibial Nerve Evoked Potentials

Start date: Aug 93	Estimated completion date:
Principal Investigator: Paul D. Mongan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of desflurane on the amplitude and latency characteristics of multimodality sensory evoked potentials.

Technical Approach: Study design, population, methods and specifics covered in protocol.

Progress: Two patients enrolled thus far. Anticipate completion in 4-5 months.

**Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-120      **Status:** Ongoing

**Title:** Menstrual Cycle Impact Upon Breast Cancer - Women - Surgery Balance

<b>Start date:</b> Aug 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Johnny Alvarez, M.D.	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Surgery/General Surgery	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** The prospective observational study described by this protocol will carefully document the menstrual cycle stage of breast cancer or benign breast biopsy and/or breast cancer resection and measure cellular and humoral activities known or suspected to affect metastatic potential in patient samples obtained before and following that biopsy and/or resection.

**Technical Approach:** Study design, treatment plan/flow, clinical evaluation/follow-up, and specifics outlined in protocol.

**Progress:** Awaiting final MRDC approval.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-48-90                      Status: Ongoing

Title: Evaluation of a Novel Aminoglycoside Dosing Nomogram.

Start date: 27 Mar 90	Estimated completion date:
Principal Investigator: Thomas C. Shank, CPT, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Pharmacy Service	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 7  
 Periodic review date: n/a                      Review results: \_\_\_\_\_

Objective(s): To evaluate the predictive accuracy of a novel aminoglycoside dosing nomogram.

Technical Approach: Adult male and female patients who have an infection requiring gentamicin will be admitted to the study. When the patients' serum gentamicin level has reached steady state, one of the study participants will administer one dose of gentamicin via a syringe pump and draw both nadir (trough) and peak serum gentamicin samples. Each sample will be divided into two parts, one will be sent to the DPALS laboratory for routine analysis and the other will be analyzed in DCI by one of the study participants.

Progress: No new patients have been enrolled in this protocol; however, I would like to keep the protocol open.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-79-91                      Status: Completed

Title: The Effects of Therapeutic Application of Heat or Cold Followed by Static Strength on Hamstring Muscle Strength.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Teresa Brashear, 2LT, SP	Facility: Academy of Health Sciences
Department/Service: Physical Therapy Section	Associate Investigator(s): Brent F. Taylor, 2LT, SP Christopher A. Waring, 2LT, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether therapeutic application of superficial heat or superficial cold prior to static stretch will increase the efficacy of the stretch in increasing hamstring muscle length in a population of healthy active duty military subjects and if a difference exists, determine which treatment is more effective.

Technical Approach: This study will examine 12 male and 12 female active duty military subjects, age 20-35. Each subject will be treated on three separate occasions. During each session, the subjects will receive one of three treatments: heat application followed immediately by static stretch, cold application followed immediately by static stretch, or static stretch alone which will serve as the control.

Progress: Principal investigator has PCSd. 24 subjects completed the study. All 3 conditions (ice, heat, stretch) resulted in an increased hamstring muscle length; no conditions increased length more than another.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-81-91                      Status: Completed

Title: Relationship Between Isokinetic and Functional Test of the Quadriceps.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Scott Shaffer, 2LT, SP	Facility: Academy of Health Sciences, Texas
Department/Service: Physical Therapy Section	Associate Investigator(s): Eric Payne, 1LT, SP Lewis Gabbard, 1LT, SP Matthew Garber, 2LT, SP
Key Words: Neuromuscular adaptation Functional testing	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 57  
 Total number of subjects enrolled to date: 57  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if eccentric and concentric isokinetic tests of the right quadriceps muscle of a healthy active duty military male population have a significant correlation with functional tests.

2) To determine if there is a statistically significant learning effect which occurs with the functional test.

Technical Approach: This descriptive study is to determine whether a correlation exists between peak torque values and values from three isotonic functional tests: 1) one legged hop for distance, 2) cross-over hop for distance, and 3) one legged triple jump for distance. One hundred health male active duty military personnel between 18 and 45 years will be tested on the Kin/Com isokinetic dynamometer at speeds of 60 and 180 degrees per second. Isotonic functional tests will be measured during the same isokinetic testing session.

Progress: Principal investigator has PCSd. This report should have been marked "completed". Manuscript has been submitted to JOSPT.



### Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: C-92-76

Status: Completed

Title: The Effects of Pulsed Magnetic Fields on Isokinetic Performance of the Quadriceps Femoris

Start date: Jul 92	Estimated completion date: Mar 93
Principal Investigator: 2LT Shari L. Fox, BSC, USAMEDD Ctr&Sch	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): 2LT Brian Boutilier, SP 2LT Julie Johnson, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20  
Total number of subjects enrolled to date: 20  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to assess the effects of pulsed magnetic fields (PMFs) on time to peak torque, peak torque, and the number of repetitions to 50% of maximum peak torque of the quadriceps femoris.

Technical Approach: Subjects will consist of 20 healthy male service members between 18 and 40 years of age. Subjects with cardiac pacemakers, cardiac arrhythmias, or metallic implants will be eliminated from the study. Subjects will be screened for previous history of knee or quadricaps muscle pathology and will not be using tobacco products or medication currently.

Progress: No significant difference in time to peak torque. Significant increase in number of repetitions to fatigue suggests that PEMF delays onset of skeletal muscle fatigue by altering blood flow, thus delaying acidosis. Principal investigator has PCSd.

# Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-77 Status: Completed

Title: Effects of Quadriceps Muscle Length on Hand-Held Dynamometer Torque Measurements

Start date: Jul 92	Estimated completion date: Mar 93
Principal Investigator: 2LT JoAnn Tymeson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, USAMEDD Ctr & Sch	Associate Investigator(s): 2LT Barbara Syler, SP 2LT Holly Hammen-Glese
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 44  
 Total number of subjects enrolled to date: 44  
 Periodic review date: Review results:

Objective(s): To determine the effect of different angles of knee flexion on the isometric quadriceps peak torque values obtained from a hand-held dynamometer (HHD) and isokinetic dynamometer (IKD). If there is an observed difference in HHD and IKD peak torque values, the contributions of strength, height, weight, and gender of the HHD tester will be determined.

Technical Approach: Pilot study will be performed by the investigators to establish the reliability of the method used to assess the upper body strength of the testers. The force transducer of the KINCOM will be set up to simulate the position of the subject's leg during an isometric contraction of the quadriceps muscles.

Progress: 43 subjects were tested by 43 testers. On 60% of the trials, the tester was unable to keep the HHD stationary. There was no significant difference between the HHD & IKO at 30 degrees; the IKO recorded significantly greater values at 60, 90, and 110 degrees. The HHD may be a valid tool only at specific points in the range of motion. Principal investigator has PCSd.

**Detail Summary Sheet**

**Date:** 15 Dec 93                      **Protocol Number:** C-92-79                      **Status:** Completed

**Title:** Comparability of Work Output Measures as Determined by Isokinetic Dynamometry and a Closed Kinetic Chain Exercise

<b>Start date:</b> Jul 92	<b>Estimated completion date:</b> Mar 93
<b>Principal Investigator:</b> ENS Michael D. Rosenthal, SP	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Physical Therapy, USAMEDD Ctr & School	<b>Associate Investigator(s):</b> ENS Lawrence L. Baer, SP 2LT Penny P. Griffith, SP ENS Frederik D. Schmitz, SP
<b>Key Words:</b> Closed kinetic chain exercise , lateral step-up, open kinetic chain exercise, work, isokinetic dynamometry	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 40  
**Total number of subjects enrolled to date:** 40  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the magnitude of the relationship between work output measured by a Later Step-Up Test and the work output measured by an Isokinetic Dynamometer test over a given time interval.

**Technical Approach:** Sixty subjects with no history of knee pathology will be screened by performing one squat to 90 degrees knee flexion, 10 standing toe raises, and 10 one-legged hops, all performed with the extremity to be tested.

**Progress:** 40 subjects tested. Correlation between work on step-up test and isokinetic dynamometer was 0.74. **Implication:** Field test (lateral step-up) may not accurately predict isokinetic work. Principal investigator has PCSd.

### Detail Summary Sheet

Date: 1 Dec 93 Protocol Number: C-93-16 Status: Ongoing

Title: Comparison of Four Treatment Approaches for Adhesive Capsulitis of the Shoulder

Start date: 14 Dec 92	Estimated completion date:
Principal Investigator: Gail Deyle	Facility: Brooke Army Medical Center, Texas
Department/Service: Phys Med/Physical Therapy	Associate Investigator(s): John Halle Jean Bryan
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of routine conservative treatments on adhesive capsulitis of the shoulder. Four treatment approaches will be contrasted, with results based on objective measures of passive range of motion and pain assessment as measured with a visual analog scale.

Technical Approach: Investigation of the response of shoulders with adhesive capsulitis will be examined over a 24 month treatment period. Effectiveness will be assessed over time and summarized both for the short term response (under six months), and for the long term outcome (from six months to two years). The dependent variables assessed will be passive shoulder range of motion, and pain as assessed with a visual analog scale. Visual analog scales have been validated as ratio scale measures for both chronic and experimental pain. Range of motion will be assessed on the involved shoulder for flexion, extension, abduction, internal and external rotation. Further specifics in protocol.

Progress: To date have been unable to recruit volunteers into this research project. Will continue to attempt to identify potential subjects and request their participation.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-107      Status: Completed

Title: Oxygen Uptake During Backward Walking at Various Speeds

Start date: Aug 93	Estimated completion date:
Principal Investigator: Glen D. Myatt, M.D.	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Richard E. Baxter Roger W. Dougherty Glenn N. Williams
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25  
 Total number of subjects enrolled to date: 25  
 Periodic review date: \_\_\_\_\_ Review results: Completed

Objective(s): Research question: What is the relationship between backward walking speeds (2.0, 2.5, 3.0, 3.5, and 4.0 miles per hour) and oxygen uptake?  
 Study design: 1) This will be a descriptive study. Descriptive statistics will be calculated. A regression analysis will be used to determine the relationship among variables. The independent variable is backward walking speed. The dependent variable is oxygen uptake; 2) Medications used: None; 3) Subject population: Normal, healthy, male volunteers.

Technical Approach: Patient criteria, methods, and specifics included in protocol.

Progress: Data collection was completed on 3 Sep 93. Currently developing research paper for review and future publication purposes. Clinical findings of the study included: a. the relationship between backward speed and oxygen consumption is described by a second order equation (quadratic); b. the relationship between backward speed and heart rate is described by a fourth order equation; c. backward walking may be utilized to maintain cardio-pulmonary fitness while decreasing the forces placed on the knee.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-108      Status: Completed

Title: Influence of Prophylactic Back Orthosis on Lifting Capabilities

Start date: Aug 93	Estimated completion date: 10 Nov 93
Principal Investigator: Gino Chincarini	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Jonelle E. Jozwiak Tami L. Roehr Bryan P. Whitesides
Key Words: Isometric lifting Lumbasacral support Back orthosis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 31  
Total number of subjects enrolled to date: 31  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Research question: does the wearing of a prophylactic back orthosis alter isometric lifting capability?  
Study design: A Latin square design will be employed. Subjects will be tested in each of the three tests positions (arm, torso and leg lift) during the first session. Subjects will be retested with a different prophylactic back orthosis condition during the second test session. The Latin square design will allow us to test for an order effect. Our Latin square design is a counter balanced, test-retest under two conditions, within subjects design (AxBxS).

Technical Approach: Null hypothesis, research hypothesis, description of subjects/controls and specifics included in protocol.

Progress: All subject testing ws completed 10 Nov 93.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-109                      Status: Ongoing

Title: Phonophoretic Delivery of 10% Hydrocortisone Through the Epidermis as Determined by Blood Cortisol Concentrations

Start date: Aug 93	Estimated completion date:
Principal Investigator: Anthony C. Bare	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Allyson E. Pritchard Maire B. McAnaw Jeffrey G. Struebing
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23  
 Total number of subjects enrolled to date: 23  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if phonophoresis transcutaneously delivers topically applied hydrocortisone cream in healthy humans. An aquasonic gel coupling agent containing 10% hydrocortisone will be used during a standard (clinical) ultrasound treatment to determine if the medication is delivered through the skin. Serum cortisol levels before, during and after treatment will be compared to one other control treatment in a 2 x 2 within subjects ANOVA.

Technical Approach: Subjects, exclusion, experimental design, procedures, data collection and specifics outlined in protocol.

Progress: Significant amounts of cortisol did not penetrate the skin as evidenced by serum cortisol assays. There was no significant drug effect or significant interaction between drug and time. All treatments have been tolerated well by the subjects with no adverse affects. Two problems have been experienced during the study: occasionally the blood may clot within the catheter and the catheter may puncture the vein allowing some saline into the tissues. The first problem has been remedied by conducting one extra 2 cc saline flush between blood draws. The second problem has been eliminated by maintaining the treatment arm in as stationary a position as possible. Due to failure to collect blood because of one of the above reasons we had incomplete





C-93-109 (continued)

data on four subjects. The data for two subjects is still awaiting lab analysis. The result is an n of 17 for our statistical analysis.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-110      Status: Completed

Title: The Effects of Unilateral Quadriceps Femoris Strength Training on Motor Performance of the Contralateral Leg in Hemiplegia

Start date: Aug 93	Estimated completion date: 11 Dec 93
Principal Investigator: Tammy McKenzie, SP	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Mary Adams David Johnson Mark Deysher
Key Words: Hemiplegia, cross- education, motor perfor- mance, lower extremity	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 8  
 Total number of subjects enrolled to date: 7  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Research question: Does an eight week progressive resistance strength training program of the uninvolved quadriceps femoris muscles in an individual with hemiplegia affect the peak torque output of the quadriceps femoris muscles of the involved leg.

Technical Approach: Subject population, medical application, status and other details outlined in protocol.

Progress: Data collection completed 11 Dec 93. Manuscript in process.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-111      Status: Ongoing

Title: Spinal Mobilization in Entry Level Physical Therapy Curricula

Start date: Aug 93	Estimated completion date:
Principal Investigator: D. Lyle McClune, ENS MSC USN	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Susan Romito
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) How are entry level physical therapy programs meeting the new 1992 "competency in mobilization" requirement established by the American Physical Therapy Association (APTA)? 2) What quantitative changes have occurred in spinal mobilization entry level curricula from 1986-1993?

Technical Approach: The purpose of this study is to determine what effect the "competency in mobilization" requirement, established by the APTA, has had on the instruction of spinal mobilization in entry level physical therapy programs. This descriptive study will provide specific information on spinal mobilization education. The information will be collected by way of a mail survey. Further specifics in protocol.

Progress: Project is progressing as outlined in protocol. Telephone survey/solicitation for participation has been completed. Currently conducting pilot survey which includes the 10 physical therapy programs here in the state of Texas. Mailed out questionnaires to the remaining 116 participating schools 1 Oct 93. Expect to have results in Dec 93.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-112      Status: Ongoing

Title: Open and Closed Kinetic Chain Force Comparisons for Concentric and Eccentric Isokinetic Squatting in Young Adult Females Using Kinetic Communicator

Start date: Aug 93	Estimated completion date:
Principal Investigator: Howard A. Rice, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Sharon J. Rogers
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 7  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Research questions: What is the relationship between open and closed chain isokinetic testing for concentric isokinetic contractions, and 2) what is the relationship between open and closed chain isokinetic testing for eccentric isokinetic contractions?

Technical Approach: Study design, subject population, equipment, etc, outlined in protocol.

Progress: Total of 70 subjects will be studied.

# Detail Summary Sheet

Date: 1 Dec 93      Protocol Number: C-93-114      Status: Completed

Title: The Effects of Iontophoresis of Prednisolone Sodium Phosphate on Serum Cortisol Concentration

Start date: Aug 93	Estimated completion date:
Principal Investigator: Chu Hyon Soh, BSC, USAF	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Kathy A. Berlin, ENS Marsha L. Bloodworth Cara M. Papahronis, SP Julie M. Whitman, BSC
Key Words: Iontophoresis, Predni- solone, Hydektrasol, Serum, Cortisol	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 20  
Total number of subjects enrolled to date: 20  
Periodic review date: Review results: Completed

Objective(s): Research Question: Does iontophoresis of prednisolone sodium phosphate as applied clinically result in the transfer of corticosteroids through the skin?

Technical Approach: Null hypothesis, research hypothesis, subjects, exclusion criteria, etc, outlined in protocol.

Progress: All data collection has been completed. Status report submitted 3 Sep 93. Final research report is in progress and will be submitted for publication upon completion.

# Detail Summary Sheet

Date: 1 Dec 93                      Protocol Number: C-93-138                      Status: Ongoing

Title: Use of an Anti-Spasmotic Medication (Dicyclomine) Prior to Flexible Sigmoidoscopy

Start date: Tentative Jan 94	Estimated completion date: Dec 95
Principal Investigator: John D. Cowsar, D.O.	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physicians Assistant Br, AMEDDC&S	Associate Investigator(s): Donna M. Corvette, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To demonstrate that the pre-administration of dicyclomine prior to flexible sigmoidoscopy can reduce patient discomfort due to bowel spasm during the procedure. The hypothesis is that the anticholinergic, dicyclomine, is significantly more efficacious than placebo in reducing pain during flexible sigmoidoscopy. Another objective of this study is to measure the pressure of air administered through the sigmoidoscope to insufflate the bowel lumen and attempt to correlate these air pressure measurements with degree of patient discomfort and depth of instrument insertion achieved by the operator. The study population which will be observed is comprised of adult women who have flexible sigmoidoscopies performed in the gastrointestinal clinic at Brooke Army Medical Center.

Technical Approach: The hypothesis of this clinical study is that dicyclomine is significantly more efficacious than placebo in reducing discomfort due to bowel spasm, thus allowing a greater depth of scope insertion than placebo during flexible sigmoidoscopy.

Progress: Cannot begin until equipment necessary is delivered.

Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-7 Status: Ongoing

Title: Comparison of Cimetidine, Ranitidine, and Diphenhydramine in the Treatment of Acute Urticaria Over a Seventy-Two Hour Period

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: CPT Anthony Ferrara, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words: Cimetidine Urticaria Ranitidine Diphenhydramine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 18

Periodic review date: Review results:

Objective(s): To determine the effectiveness of cimetidine, ranitidine and diphenhydramine in the treatment of acute urticaria during the immediate ER follow-up period.

Technical Approach: Subjects in this study will include 120 male and female patients between the ages of 16 and 55 presenting to the Emergency Room at Darnall Army Community Hospital with signs and symptoms consistent with acute urticaria of less than 24 hour duration. Presenting symptoms should include itching, swelling, and rash.

Progress: Study still ongoing for patient enrollement.

### Detail Summary Sheet

Date: 15 Dec 93 Protocol Number: C-92-46 Status: Terminated

Title: Dental Liquid Ration Test (Natick Study)

Start date: 1 May 93	Estimated completion date: 1 May 94
Principal Investigator: CPT Carol J. Baker, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Nutrition Care, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words: Liquid Ration Test	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Estimates of food and fluid consumption will be collected and subjects' nutrient intakes will be compared with the Military Recommended Dietary Allowances. Nutrient intakes of non-military personnel will be compared to the Recommended Dietary Allowances.

Technical Approach: Subjects will consist of approximately 150 patients 18 years old or above (300 patient equivalent days) in military and veterans hospitals and, in addition, a minimum of 25 geriatric and 25 cancer patients (100 patient equivalent days) who would ordinarily be consuming a liquid and/or pureed diet during their hospital stay.

Progress: Study was never initiated.



# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-71                      Status: Completed

Title: Urinary Toxicologic Screening After Dermal Exposure to Cocaine

Start date: 15 Aug 92	Estimated completion date:
Principal Investigator: CPT Laurel Kietzman, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s): Brian Baxter, MD Carolyn Tiffany, MD Trudi McGrath, MD Jay Still, MS
Key Words: Cocaine Tox Screen	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 39

Total number of subjects enrolled to date: 39

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether dermal exposure to an 11.8% cocaine solution followed by cleansing with alcohol and IV angiocath insertion, produces detectable urinary levels of benzoylecgonine.

Technical Approach: Project design is a prospective, quantitative data collection which will involved 40 adult volunteers between ages 18-65.

Progress: Data were analyzed for differences in cocaine levels between collection times using one-way ANOVA with paired comparisons using Wilcoxon Signed Rank Test. If ANOVA reached significance; p = 0.05 was significant. No subjects were found to be positive by National Institute of Drug Abuse (NIDA) Standards. There were detectable levels of cocaine or cocaine metabolites found in urine samples at 24 hours, 48 hours and 7 days from TAC application. This would suggest that cocaine 11.9% in TAC solution would not produce false positive screening tests for cocaine.

# Detail Summary Sheet

Date: 15 Dec 93                      Protocol Number: C-92-87                      Status: Ongoing

Title: Comparison of Intramuscular Meperidine and Chlorpromazine, With and Without Promethazine for Pediatric Sedation

Start date: 1 Oct 92	Estimated completion date: 1 Oct 93
Principal Investigator: CPT William D. Rodriguez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s): MAJ Daniel J. Dire, MC
Key Words: Meperidine; Chlorpromazine; Promethazine; Pediatric Sedation	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 30  
 Periodic review date: 1 Oct 93      Review results: \_\_\_\_\_

Objective(s): To determine if there is a significant difference in the efficacy of sedation and frequency of complications after intramuscular meperidine and chlorpromazine, with and without promethazine (MC vs MPC).

Technical Approach: Pediatric ED patients will be preselected upon their arrival to the ED based on a set criteria for entry into study. Patients entering the study will be greater than 1 year of age and less than 16 years of age having one or more of indications outlined in study.

Progress: Total of 30 patients enrolled to date. No adverse side effects.

# **Detail Summary Sheet**

**Date:** 1 Dec 93      **Protocol Number:** C-93-128      **Status:** Ongoing

**Title:** A Prospective Randomized Double-Blinded Evaluation of Prochlorperazine versus Sumatriptan for the Emergency Department Treatment of Migraine Headache

<b>Start date:</b> 16 Aug 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Kevin Hammond, M.D.	<b>Facility:</b> Darnall ACH & Brooke Army Medical Center, Texas
<b>Department/Service:</b> Emergency Medicine	<b>Associate Investigator(s):</b> David B. Cline, M.D. Margaret J. Karnes, D.O. Donald M. Yealy, M.D. Marco Coppola, M.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 19  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the relative efficacy of prochlorperazine versus sumatriptan for the emergency department treatment of migraine headache.

**Technical Approach:** Patients between the ages of 18 and 60 who present to our Emergency departments with a migraine headache as defined by the Ad Hoc Committee on Classification of Headache will be entered into the study. Patients with certain conditions outlined in protocol will be excluded.

**Progress:** Collecting data.

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